S. HRG. 108–218

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2004

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

ON

H.R. 2660/S. 1356

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES, FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2004, AND FOR OTHER PURPOSES

Department of Education
Department of Health and Human Services
Department of Labor
Nondepartmental witnesses

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2004

WEDNESDAY, MARCH 19, 2003

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:01 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senator Specter, Craig, Gregg, Harkin, Landrieu, and Kohl.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF TOMMY G. THOMPSON, SECRETARY OF HEALTH AND HUMAN SERVICES

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The hearing of the Appropriations Subcommittee of Labor, Health, Human Services, and Education will now proceed.

Our witness today will be the Secretary of HHS, Secretary Tommy Thompson, the 19th Secretary of the Department which oversees the health and welfare of the Nation.

The administration budget has proposed a discretionary account for the Department of Health and Human Services of some $60.7 billion which constitutes an increase of $514 million over the fiscal year 2003 level, which, as obvious, does not even account for an inflationary increase.

This Department has some of the most important funding in our Nation, spanning medical research and Head Start and the low-income health and energy costs, known as LIHEAP, and a broad range of very, very important programs. It is, as usual, a very difficult matter in allocating the resources which this subcommittee has for three Departments, the Department of Education, the Department of Labor, in addition to this Department.

There is special concern about a number of lines. The Centers for Disease Control, which is being asked to take on additional responsibilities, as we speak, with this outbreak in China. The National Institutes of Health, which have had extraordinary results, have been limited in this year's suggested funding by the administration

to a $673 million increase, which is a sharp decrease from the $3.5 billion increase which the administration requested last year, which really was a commentary on the phenomenal results which NIH had. But we will be wrestling with these issues.

We appreciate the appearance of the Secretary today. To give the maximum time for the Secretary's comments, we will begin at this point.

Secretary Thompson began his public service back in 1966 as a representative in the Wisconsin State Assembly. He served as Governor of Wisconsin from 1987 to 2000, the longest-serving Governor in Wisconsin history, well known for his innovative activities in the welfare system and expanding health care access to low-income children and families. He was chairman of the National Governor's Association, the Education Commissioner of the States and Midwestern Governors Conference. Both of his degrees, bachelor and J.D., come from the University of Wisconsin at Madison.

Thank you for joining us, Mr. Secretary, and we look forward to your testimony.

SUMMARY STATEMENT OF HON. TOMMY G. THOMPSON

Secretary THOMPSON. Thank you so very much, Mr. Chairman. I want to thank you at the outset for your passion, for your leadership on so many issues that are very important to the future of the health care and well-being of Americans, and I thank you for that leadership.

I am sorry Mr. Harkin is not here, but I also want to extend my appreciation to him as well.

Thank you so very much, Senator Specter, for inviting me to testify today.

In my first 2 years at the Department, we have made, I believe, tremendous progress in our efforts to improve the health, the safety, and the well-being of the American people. We continue to make extraordinary progress in providing health care to lower-income Americans through waiver and State plan amendments granted to States. We have been able to expand access to health coverage for more than 2.2 million individuals and have expanded the range of benefits offered to an additional 6.7 million other Americans.

To build on this progress, the President proposed outlays for HHS of $539 billion. $539 billion represents an increase of $36.8 million, or 7 percent over last year's request, an increase of more than $109 billion, or 25 percent, since 2001.

The discretionary part of the budget increases $1.64 billion, or 2.6 percent, to $65 billion of budget authority. This would be $606 million, or 1.5 percent, higher than what was enacted by the Congress in the fiscal year 2003 appropriation bill.

$539 billion is a large number, and I have a solemn responsibility as Secretary to make sure that every one of those dollars is put to good use. I owe it to the people who pay the taxes, and I owe it to the people who consume the services.

One way to ensure that these dollars are effective is to work with you, Senator Specter, and Senator Harkin and other committee members and other committees to improve and strengthen our two largest health programs, Medicare and Medicaid. I discuss these programs in my written testimony.

We are also making progress in keeping health care costs down and preventing chronic diseases by encouraging Americans to lead healthier lives. We have all heard the disturbing news about the prevalence of diabetes, obesity, and asthma that could be prevented through simple lifestyle changes. Diabetes alone costs the Nation nearly $132 billion each year in direct medical and indirect economic costs. Yet, modest lifestyle changes, such as getting more exercise and losing weight, can reduce the risk of this and other diseases dramatically.

The HHS budget, consistent with the President's HealthierUS effort, proposes a coordinated Department-wide effort, Steps to a HealthierUS, to promote healthier lifestyles, emphasizing prevention of obesity, diabetes, asthma, heart disease, stroke, and cancer. The fiscal year 2004 budget includes an investment of $125 million for targeted disease prevention.

In order to improve patient safety, which I know, Senator Specter, you have been an advocate and leader on, the Food and Drug Administration is proposing two new rules to prevent errors with medication.

The first of these proposals will require bar-coding on almost all pharmaceuticals and blood products. This rule would help reduce the number of medication errors by allowing health care professionals to use bar-code scanning equipment to verify that the right drug in the right dose is given to the right patient at the right time.

We also support the creation of patient safety organizations in order to collect data that can improve procedures and prevent errors.

And thanks to your strong support, Mr. Chairman, we recently completed a doubling of the budget of the National Institutes of Health. This year we continue that commitment with a budget of $27.7 billion, a net increase of $549 million over last year.

But as a result of one-time projects that were funded in fiscal year 2003 and not needing to be refinanced, actual NIH research investment will rise by $1.9 billion, or 7.5 percent.

I would like to focus the remainder of my remarks this morning on a topic that is probably on everyone's mind this week, and that is bioterrorism. I would like to offer to you, Mr. Chairman, and members of the committee, an opportunity to come over to the Department at your choosing to see our new bioterrorism communications center. It is state of the art, and it is one that you would appreciate if you would come over and have an opportunity to see.

The attacks on September 11 made it clear that the threat of terror is more grave and more imminent than at any time in modern history. Anthrax attacks make it clear that the threat of terrorism includes weapons of unprecedented power and ingenuity, and the proliferation of weapons of mass destruction in the hands of outlaw regimes makes it even more urgent that we prepare for a growing variety of threats.

We have already done a great deal, and the United States today is better prepared than ever to meet and be able to respond to the threat of a terrorist attack with a biological, chemical, radiological, or nuclear agent.

The National Stockpile of Medical Countermeasures is large and getting more extensive all the time. But that stockpile may not be enough. Unfortunately, the medical treatment available for many pathogens have improved very little in decades. The smallpox vaccines available today hardly differ from those of the 1960s. Some treatments for radiation and chemical exposure have not changed much since the 1970s, and some diseases, such as ebola, have never had an effective medical countermeasure. These diseases lack effective or modern treatment in part because they are so rare.

By contrast, the treatment of the vast majority of common, naturally occurring illnesses have been able to be improved dramatically as a result of ongoing innovations from biomedical research and development. Heart attacks were often fatal in the 1970s, but they are much less so today. And better detection and therapeutic options have significantly improved survival rates for many kinds of cancer over the last 20 years.

We must bring that sort of progress to the rare, yet deadly threats which are posed by bioterrorists, and that is why President Bush, with the help of my Department, has been able to announce Project Bioshield. He would spend roughly $6 billion over 10 years on new countermeasures to prepare America for a bioterrorist attack. This proposal would speed up research and approval of vaccines and treatments and ensure a guaranteed funding source for their purchase, just the latest in our forward-looking efforts to protect the homeland.

Our Department is doing well at getting bioterrorism money out to State governments in many cases faster than they are able to spend it.

So as we speak, Mr. Chairman, researchers are working to identify the cause of the recent cases of what has been called severe acute respiratory syndrome. While we have no reason to think that this syndrome is related to influenza, the appearance of similar symptoms in scattered locations reminds us that this is the way an influenza pandemic might start.

The President's budget foresaw and prepared for an influenza outbreak. It proposes to spend $100 million to ensure the Nation has an adequate supply of influenza vaccine in the event of a pandemic. And due to the constant changes in the circulating influenza strains, we cannot stockpile influenza vaccine, and the current manufacturing methods could not meet the Nation's needs in the event of a pandemic. Funds will be used for activities to ensure a year-around influenza vaccine production capacity and development and implementation of rapidly expandable production technologies. We will work closely with industry to accomplish these goals.

The President has made improving our Nation's health and health care one of his biggest priorities for this year. By working together, we can make it one of our proudest achievements.

I look forward to working with you, Mr. Chairman, Senator Harkin, as well as Senator Craig, and all members of this committee, and I know our discussion this morning will certainly proceed and allow those things to be initiated.

PREPARED STATEMENT

I thank you, Mr. Chairman, and I would also, once again, invite you and other members of the committee to come over to the Department and see our very modern, state-of-the-art communications system that will allow us to better respond to any bioterrorist attack that may take place in this country. Thank you again for giving me this opportunity to appear in front of you, Senator.

[The statement follows:]

PREPARED STATEMENT OF TOMMY G. THOMPSON

Good morning Mr. Chairman, Senator Harkin and members of the committee. I am honored to be here today to present to you the President's fiscal year 2004 budget for the Department of Health and Human Services (HHS). I am certain you will find that, viewed in its entirety, our budget will help improve the health and safety of our Nation. Before I discuss the fiscal year 2004 budget, I would like to thank the committee for its hard work and dedication to the programs at HHS.

Our fiscal year 2004 request totals $539 billion in outlays, approximately 7.3 percent over the fiscal year 2003 budget. The discretionary budget authority portion of the HHS budget, before this committee, totals $60.7 billion, which is an increase of approximately $1.5 billion, or 2.6 percent over the fiscal year 2003 President's Budget and an increase of approximately $514 million, or 0.9 percent over the fiscal year 2003 enacted appropriation. Mandatory outlays for HHS total $475.9 billion in this budget proposal, an increase in excess of 7 percent.

The budget proposed by the President for HHS will enable the Department to continue its important work with our partners at the State and local levels and the newly created Department of Homeland Security. Working together, we will hold fast to our commitment to protecting our Nation and ensuring the health and well-being of all Americans. Many of our programs at HHS provide necessary services that contribute to fighting the war on terrorism and provide us with a more secure future. And, I am particularly focused on preparedness at the State and local level, HHS's ability to respond rapidly to a bioterrorist attack, research on and development of vaccines and other therapies to counter potential bioterrorist attacks, and ensuring the safety of our food supply.

The President's fiscal year 2004 budget request also continues to support the needs of the American people by strengthening and improving Medicare and Medicaid; enhancing Temporary Assistance for Needy Families (TANF) and Foster Care; strengthening the Child Support Enforcement Program; and furthering the reach of the President's New Freedom Initiative.

The support of your committee is vital to achieving many of the Administration's most important priorities. I am grateful for the close partnership we have enjoyed in the past, and I look forward to working with you again on an aggressive appropriations agenda to advance the health and well being of millions of Americans. Today, I would like to highlight for you the key issues in the President's budget.

SUPPORTING THE PRESIDENT'S DISEASE PREVENTION INITIATIVE

One of the most important issues on which we can work together is chronic disease prevention. We all have heard the disturbing news about the prevalence of diabetes, obesity, and asthma that could be prevented through simple lifestyle changes. The statistics, I am sure, are as alarming to you as they are to me. For example, the incidence of diabetes and obesity among Americans is up sharply in the past decade, putting millions more Americans at higher risk for heart disease, stroke and other related medical conditions.

Diabetes alone costs the Nation nearly $132 billion each year in direct medical costs and in indirect economic costs, including disability, missed work, and premature death. Medical studies have shown that modest lifestyle changes—such as getting more exercise and losing weight—can reduce an individual's risks for developing this serious health conditions.

The HHS budget, consistent with the President's HealthierUS effort, proposes a coordinated, Department-wide endeavor—Steps to a HealthierUS—to promote healthier lifestyles emphasizing prevention of obesity, diabetes, asthma, heart disease, stroke, and cancer. The fiscal year 2004 budget includes an investment of $125 million for targeted disease prevention.

IMPROVING THE NATION'S HEALTH

Of all the issues confronting this Department, none has a more direct impact on the well being of our citizens than the health of our Nation. Our budget makes a concerted effort to improve the health of the American people by taking significant steps that include: reducing prescription drug-related medical costs, financing vaccines, investing in hospital information technology, and continuing the effort to increase and expand the number of Health Centers.

The budget includes initiatives that will carry out the Best Pharmaceuticals for Children Act (BPCA) and alleviate drug-related medical costs. My budget request for NIH includes an additional $25 million, for a total of up to $50 million, to improve information available for prescribing pharmaceuticals to children. NIH is focusing its efforts on drugs that are no longer under patent. The request for the Food and Drug Administration (FDA) includes $12.3 million to increase Americans' access to safe, effective, and less expensive generic drugs and a $1 million increase to expand the range of drugs available over-the-counter.

The HHS budget includes a series of improvements in the financing of childhood vaccines to meet three goals—(1) improve vaccine access for currently eligible children, (2) restore tetanus and diphtheria booster vaccines (Td, DT) to the Vaccines for Children (VFC) program, and (3) build a national stockpile of childhood vaccines. Legislation will be proposed to improve access to VFC vaccines for children already entitles to them. The budget proposes to expand the number of access points for underinsured children—those whose private insurance does not cover the immunizations—by allowing them to receive their VFC vaccines at State and local public health clinics. To help protect against future shortages, HHS will, starting in fiscal year 2003, develop a stockpiling strategic plan and begin building a vendor-managed, 6-month supply of all childhood vaccines to be completed by 2006. The budget includes $707 million in fiscal year 2003 to 2006 for the stockpile. Under current-law we can stockpile these vaccines. I also propose to restore the tetanus and diphtheria booster shots to the VFC program by removing outdated price caps that are so low for some vaccines that vendors will not bid on VFC contracts.

The budget also contains $100 million to ensure the nation has an adequate supply of influenza vaccine in the event of a pandemic. Due to the constant changes in the circulating influenza strains, we cannot stockpile influenza vaccine, and the current manufacturing methods could not meet the Nation's needs in the event of a pandemic. Funds will be used for activities to ensure a year-round influenza vaccine production capacity and the development and implementation of rapidly expandable production technologies. We will work closely with industry to accomplish these goals.

Senator Specter, you were instrumental in ensuring that patient safety is a primary focus of AHRQ's research portfolio. In fiscal year 2001, we made awards to 94 grantees in five areas to begin the first of three years of research to improve patient safety across healthcare settings. Nearly half of these demonstration projects are focusing on the use of computers and information technology to prevent medical errors and to improve reporting of medical errors data Through these projects, grantees are piloting potential error-reducing technologies like personal digital assistants (PDAs) for electronic prescription writing, as well as Computerized Physician Order Entry (CPOE), a technology that helps to ensure that patients receive the right medication, at the right dose, at the right time. As a result of these projects, AHRQ's first step in improving patient safety has been to demonstrate the efficacy of certain interventions in reducing medical errors.

Our next step must be to take what we have learned and disseminate it to healthcare providers and networks. We are putting $50 million into a new program at AHRQ that will improve patient safety by increasing investments in hospital information technology. We are also making a commitment to help implement these technologies in health systems that otherwise may not be able to make the capital investment. A focus on small community and rural hospitals will help to bridge the so-called "digital divide" by helping these hospitals catch up with those that are further along.

AHRQ's budget proposal also includes $24 million for ongoing activities such as the work of the Patient Safety Task Force and the Patient Safety Data Reporting System integration efforts, as well as plans to initiate challenge grants and a patient safety improvement corps; a $10 million increase for the expansion and enhancement of information collected in the U.S. Census Bureau's Current Population Survey; and a $2 million increase to improve the usability and timeliness of Medical Expenditure Panel Surveys (MEPS) data and help sustain prior year enhancements to the sample size and content of surveys that collect information from medical providers, insurers, and households.

We must do everything within our abilities to address the disparities in health care in this Nation. The fiscal year 2004 budget proposes numerous activities to address and alleviate health inequities. Programs that cut across various HHS agencies strive toward bettering the health of our Nation.

The fiscal year 2004 budget continues the third year of the President's multi-year initiative to expand access to care for millions of Americans especially those who are uninsured. The budget includes $1.6 billion, a $122 million increase, to provide primary and preventive health care services to nearly 14 million individuals. Almost 40 percent of the patients treated at health centers have no insurance coverage and many others have inadequate coverage. These health centers are located in our most underserved communities. Over half are in rural America. In support of the Health Center Initiative, the President is also seeking to expand the National Health Service Corps by adding $42 million to increase the number of health care providers in rural and underserved areas, to a total field strength of 4,300 people; and provide for 2,400 loan repayments and scholarships.

In addition to childhood immunization, the fiscal year 2004 President's budget for the Centers for Disease Control and Prevention (CDC) requests programmatic increases in several areas. I am seeking a $12 million increase for the breast and cervical cancer program, which supports screenings for low-income, underinsured, and uninsured women between the ages of 50–64, and $5 million to expand School Health Programs to reduce health risks such as tobacco use, poor eating habits and obesity. The budget also includes an increase of $10 million for a Public Health Information Network (PHIN) to integrate and expand CDC's existing networks to establish a consistent exchange of information between public health partners.

The Substance Abuse and Mental Health Services Administration's proposed budget is $3.4 billion, a net program level increase of $198 million over fiscal year 2003. As part of the President's Drug Treatment Initiative, the budget includes $200 million in fiscal year 2004, a total of $600 million over three years, to establish a new competitive State substance abuse voucher program. This program will assist 100,000 Americans in the first year in obtaining the critical alcohol and drug treatment services they need but lack access to. This effort complements existing alcohol and drug abuse treatment programs by providing consumer choice and broadening the base of treatment providers to include more faith-based providers. Through this new program individuals seeking drug and alcohol treatment and support services will be assessed and then receive a voucher to pay for appropriate community treatment programs. This program will require accountability by linking payment to providers to demonstrated treatment effectiveness measured by abstinence from alcohol and drug use after treatment.

The fiscal year 2004 request also includes an increase of $31 million for the Substance Abuse Block Grant. The Block Grant will provide drug treatment services to 400,000 persons. In the area of mental health, we propose $107 million, an increase of $9 million, for Children's Mental Health Services to serve a total of 17,000 children and adolescents with serious mental and emotional disorders along with their families. We are also requesting $50 million, an additional $7 million, for Projects for Assistance in Transition from Homelessness to serve a total of 147,000 homeless individuals. These funds link efforts to move homeless individuals off the streets by providing them with mental health services and substance abuse treatment.

FIGHTING HIV/AIDS

HIV/AIDS is one of the most serious challenges facing humanity. No country has been spared. Some have faced widespread devastation. All have citizens whose lives have been destroyed by this horrible disease. Our commitment to ending this pandemic is strong and unwavering. The fiscal year 2004 budget for HHS includes $6.4 billion in discretionary funds within HHS to combat HIV/AIDS. Within this level is $680 million to support a variety of efforts to fight HIV/AIDS in developing nations. For example, our budget includes $150 million to support the Mother-to-Child transmission of HIV/AIDS prevention initiative. This initiative seeks to treat approximately one million women annually in developing countries in order to reduce transmission of HIV to their children by 40 percent. This is an integral part of the President's Emergency Plan for AIDS Relief, which seeks to stem the death toll from AIDS. Currently, demographers project that, absent strong action, life expectancy will fall from 66 to 33 years in Zambia and from 70 to 40 years in Zimbabwe.

The budget also, includes $2 billion for life sustaining care and services for over 530,000 Americans under the Ryan White CARE Act. The Ryan White programs target our resources toward the development of an effective service delivery system by partnering with States, heavily impacted metropolitan areas, faith-based and community-based providers and academic institutions. Our budget includes $739

million to provide drug therapies to approximately 159,000 individuals. These funds will provide Americans living with HIV/AIDS a lifeline to care who might otherwise have to choose between expensive medical treatments and other necessities. These funds will help eliminate those difficult decisions.

MAINTAINING OUR INVESTMENT IN BIOMEDICAL RESEARCH

I commend you, Mr. Chairman, Senator Harkin, and this Subcommittee, for your unwavering commitment to doubling the budget for the National Institutes of Health. After five years of outstanding growth that doubled the NIH budget, the fiscal year 2004 Budget provides a significant investment to ensure that the momentum gained over the last five years is sustained. We have developed a plan that would increase funding for on-going research by about $2 billion, approximately +7 percent. The fiscal year 2004 budget totals $27.9 billion, a net increase of $718 million above the fiscal year 2003 enacted appropriation. Within the NIH Budget, research grows much more rapidly, as a result of redirecting one-time project cost savings into new biomedical research funding. NIH will fund a record number of new and competing research grants. Advances in scientific knowledge have provided the foundation for improvement in public health and have led to enhanced health and quality of life for all Americans. Much of this can be attributed to the ground breaking work carried on by, and funded by, the National Institutes of Health. Some additional highlights of NIH funding include:

—Over $15 billion to fund an expected record number of research project grants (at least 10,500 for competing grants and a total of approximately 39,500 grants);
—An increase of $25 million for a total of $50 million for pediatric drug use studies;
—An increase of $50 million for Type 1 diabetes research ($150 million total in mandatory appropriation); and
—An increase of $25 million for NIH's new strategic biomedical research "roadmap".

FIGHTING BIOTERRORISM

Mr. Chairman, as Americans confront the realities of terrorism and hostilities around us, it is imperative that the Federal Government be prepared to keep our citizens safe and healthy.

HHS's $3.6 billion bioterrorism budget substantially expands ongoing medical research, strengthens State and local preparedness and targets investments to protect our food supply. State and local public health preparedness activities funded by the Centers for Disease Control and Prevention (CDC) and hospital preparedness efforts supported by the Health Resources and Services Administration (HRSA) would receive a total of $1.5 billion. The President's proposal significantly increases ongoing biodefense research at the National Institutes of Health (NIH). The budget includes a total of $1.6 billion for basic research on the biology of microbial agents with bioterrorism potential and applied research on the development of new or improved diagnostics, vaccines, and therapies. We propose increasing support for bioterrorism education for clinicians by $32 million, for a total of $60 million, to provide incentives for 25 medical and health professions curricula reform projects and provide continuing education to 65,000 health care providers on the diagnosis, treatment, and reporting of diseases that can be caused by the intentional release of a biological agent. The bioterrorism budget also includes initiatives to improve food safety: $15.5 million targeted on newly authorized activities, including registration of domestic and foreign food facilities and State grants to improve state food laboratories, monitoring and inspections; and an additional $5 million for improving information exchange with State food laboratories on food pathogens.

HHS, in cooperation with the Department of Homeland Security, will spearhead the development of Project Bioshield. This project, which the President recently announced, will bring together the scientific and fiscal resources of the United States government in an innovative effort to develop medical countermeasures against bioterror before they are ever needed. Project Bioshield will have three (3) major goals:

—To ensure that sufficient resources are available to procure the next-generation countermeasures. A guaranteed funding source must be available to enable the government to purchase vaccines and other therapies as soon as experts believe they can be made and will be safe and effective, and spur industry investment in the development of these vaccines/therapies.
—To Accelerate NIH research and development. This involves providing more flexible contracting process and procurement authorities for critical biodefense work.

—To make promising treatments available more quickly for use in emergencies. This means establishing a new FDA Emergency Use Authorization that would permit greater flexibility and latitude than the current Investigational New Drug (IND) authority in the use of promising medical countermeasures that are under development in emergency situations.

While funding for the next generation countermeasures will be in the new Department of Homeland Security (DHS), HHS will provide the scientific direction, and will be responsible for the actual procurements. Furthermore, HHS will continue to manage the Strategic National Stockpile and provide the scientific and public health direction needed to ensure that the pharmaceutical stockpiles include appropriate amounts of vaccines, other therapeutics and emergency equipment/supplies. New mandatory funding will also be included in DHS which will ensure that adequate resources are available to procure new medical countermeasures once sufficient research has been conducted to demonstrate that the products will be proven safe and effective. A guaranteed funding source must be made available to industry to stimulate interest and investment in the development of these products. This authority would be invoked only if there is no significant commercial market for the products.

HEAD START

Never has there been such a clear commitment on the part of Federal and State governments to enhance the well being of children and families. Never have we known so much about what children need for healthy growth and development. Never have so many programs been focused on meeting these needs of our most vulnerable citizens. There are more resources currently available for low-income children and families than at any other time in our nation's history. The President's budget continues this commitment with a budget of $6.8 billion to provide 923,000 children Head Start services. However, not all the news is good. Children in Head Start enter school further ahead than other economically disadvantaged children. But unfortunately—even after 30 years—Head Start children do not enter school at the same level as more economically advantaged children.

To strengthen the Head Start program, improve services to low-income children, and promote the coordination and integration of comprehensive early care and education services, President Bush is asking Congress to include in the reauthorization of the Head Start Act a provision that will allow interested states to include Head Start in their preschool plans. Under the President's proposal, states are offered the opportunity to coordinate preschool programs with Head Start programs in exchange for meeting certain accountability requirements. States wishing to participate must submit a state plan that addresses several fundamental issues concerning preschool education.

FAITH BASED AND COMMUNITY INITIATIVES

In support of the President's Faith-Based and Community Initiative, the HHS fiscal year 2004 budget supports programs that link faith- and community-based organizations, State and local governments, and Federal partners to provide effective substance abuse treatment and positive youth development.

Another important program that helps some of our most vulnerable children is the Mentoring Children of Prisoners program. We are asking for funds to be increased to a total of $50 million, which would in turn be made available to faith-based, community-based, state and local governments, tribes, and public organizations for programs that provide supportive one-on-one relationships with caring adults to children who are more likely to succumb to substance abuse, gang activity, early childbearing and delinquency. This down payment will help more than 30,000 adolescent children of prisoners receive guidance, have positive role models, and give them a fighting chance to succeed.

The President's budget also proposes $20 million for promotion and support of responsible fatherhood and healthy marriages. This funding will promote and support involved, committed, and responsible fatherhood and encourage the formation and stability of healthy marriages.

In addition, the budget request for the Compassion Capital Fund is $100 million, an increase of $65 million above the fiscal year 2003 appropriation. These funds would continue to be used to provide technical assistance to faith- and community-based organizations to expand and emulate model social programs.

STRENGTHENING AND IMPROVING MEDICARE

Even though Medicare is not under the jurisdiction of this Committee, we are all aware that our Nation's Medicare program needs to be modernized and improved to provide seniors with more choices and better benefits. While we remain stead-

fastly committed to ensuring that America's seniors and individuals with disabilities can keep their current, traditional Medicare, the President is dedicating $400 billion over ten years to provide access to subsidized prescription drug coverage, better private options for those beneficiaries who want them, full coverage for disease prevention, and better protection from high out-of-pocket costs.

Under the President's framework, seniors happy with their coverage under traditional Medicare will be able to keep it, with added protection against high out-of-pocket drug expenses at no additional premium. Seniors who want better coverage will be offered the same types of plan choices available to members of Congress and federal employees. Private plans will be available in each region of the country, including rural areas. Plans will provide full coverage of preventive care, protection against high out-of pocket medical costs, and cost sharing that does not penalize the sick. Comprehensive, subsidized prescription drug coverage will be available to those who want it for an additional premium. Low-income seniors will face no premium for drug coverage and will have only nominal cost-sharing requirements. Seniors who enroll in these plans will maintain the ability to choose any doctor and any hospital.

Seniors willing to accept a more selective provider panel will be able to enroll in the same type of low-cost, high-coverage managed care plans available today. These plans will offer a subsidized, comprehensive drug benefit, as well as all the additional benefits I just described. Plans can also offer extra benefits and broader coverage.

STRENGTHENING AND IMPROVING MEDICAID AND SCHIP

State Health Care Partnership Allotments

Another of our mandatory initiatives that I would like to briefly highlight is our plan to strengthen and improve Medicaid and SCHIP. Building on the successes of the State Children's Health Insurance Program (SCHIP) and the Health Insurance Flexibility and Accountability (HIFA) demonstrations have shown in increasing coverage while providing flexibility and reducing the administrative burden on States, the Administration proposes optional State Health Care Partnership Allotments. Under this proposal, States would have the option of electing to continue the current Medicaid program or to choose partnership allotments. The allotment option provides States an estimated $12.8 billion over seven years in extra funding over the expected growth rate in the current Medicaid and SCHIP budgets. If a State elects the allotments, the federal portion of the SCHIP and Medicaid funding would be combined and states would receive two individual allotments: one for long-term care and one for acute care. States would be required to maintain their current levels of spending on Medicaid and SCHIP, but at a lower rate of increase than the federal allotment.

States electing a partnership allotment would have to continue providing current mandatory services for mandatory populations. For optional populations and optional services, the increased flexibility of these allotments will allow each State to tailor its provision of health benefit packages for its low-income residents. Let me stress that this is an OPTION we are proposing for States.

New Freedom Initiative

Promoting home and community-based care as an alternative to nursing homes for the elderly and disabled is a priority of this Administration. The New Freedom initiative represents part of the Administration's effort to allow Americans with disabilities to be more fully integrated into their communities. Under this initiative, we are committed to promoting the use of at-home and community-based care as an alternative to nursing homes. The Administration will invest $350 million in fiscal year 2004, and $1.75 billion over 5 years on this important initiative to help seniors and disabled Americans live in the setting that best supports their needs.

Transitional Medicaid Assistance (TMA)

TMA provides health coverage for former welfare recipients after they enter the workforce. TMA allows families to remain eligible for Medicaid for up to 12 months after they lose welfare-related Medicaid eligibility due to earnings from work. This budget proposal would authorize the TMA program for five more years, at a cost of $400 million in fiscal year 2004, and $2.4 billion over five years. We are also proposing modifications to TMA provisions to simplify it and make it work better in coordination with private insurance. These modifications cost $20 million in fiscal year 2004 and $290 million over five years.

EMPOWERING AMERICA'S FAMILIES

Reauthorization of Temporary Assistance for Needy Families (TANF) and the Child Care Development Fund

Building on the considerable success of welfare reform in this great Nation, the President's fiscal year 2004 budget follows the framework proposed in the fiscal year 2003 request, which includes the reauthorization of TANF. We applaud passage of H.R. 4 and are committed to working with both the House and the Senate to ensure the legislation moves quickly and is consistent with the President's Budget. The President's proposal includes five years of funding for the TANF Block Grants to States, and Tribes; Matching Grants to Territories; and Tribal Work Programs at current levels. In addition, the Budget proposes to reauthorize state-based abstinence education grants for five years at $50 million annually, to further assist with reducing the number of out-of-wedlock births, reducing the spread of STDs among teens, and helping teens make healthy life choices.

Increasing Support for Children in Foster Care

In a continuing effort to improve the lives of children who are at risk of abuse and neglect, this Administration is proposing a child welfare program option that States can use to improve their child welfare service systems. This plan would allow States to choose a fixed allocation of funds over a five-year period rather than the current entitlement funding for the title IV-E Foster Care program. Participating States would receive their funds in the form of flexible grants which could be used for a wide array of child welfare-related purposes, such as child abuse and neglect prevention, maintenance and administrative payments for foster care, child welfare training, and family support. The flexible funding will allow States to develop innovative ways to ensure the safety, permanency and well-being of children, tailed to meet the needs of their child welfare populations. States which elect this option and experience emergencies affecting their foster care systems may access additional funding from the TANF contingency fund.

The Administration is proposing a nearly $5 billion budget for Foster Care in fiscal year 2004, a $90 million increase over last year's request. Not only will these funds support a child welfare program option, but they also will be used to provide payments for maintenance and administrative costs for more than 240,000 children in foster care each month, as well as payments for training and child welfare data systems. The President's budget also requests $200 million for the Foster Care Independence Program.

Additionally, the Administration continues its commitment to the Promoting Safe and Stable Families Program by requesting to $505 million to assist States in coordinating services related to child abuse prevention and family preservation. This important program also promotes adoption and provides post-adoption support to families.

Child Support Enforcement

The President's fiscal year 2004 budget will build on the considerable success of the Child Support Enforcement program. Legislation will be proposed to enhance and expand the existing automated enforcement infrastructure at the Federal and State level and increase support collected on behalf of children and families. When combined with the opportunities to increase child support outlined in the President's fiscal year 2003 budget (expanded passport denial, offset of certain Social Security benefits, optional pass through of child support to families on TANF, among others) these proposals offer an impressive $7.5 billion in increased child support payments to families over 10 years. The budget also recognizes that healthy families need more than just financial support and increases resources for the Access and Visitation Program to support and facilitate non-custodial parents' access to and visitation of their children.

PRESIDENT'S MANAGEMENT AGENDA

I realize that as we work to improve the heath and well-being of every American citizen, we also need to improve ourselves. I am committed to improving the management of the Department of Health and Human Services. The fiscal year 2004 budget supports the President's Management Agenda and includes cost savings from consolidating administrative functions; organizational delayering to speed decision making processes; competitive sourcing; implementation of effective workforce planning and human capital management strategies; and adoption of other economies and efficiencies in administrative operations. We have also included savings in information technology (IT) which will be realized from ongoing IT consolidation efforts and spending reductions made possible through the streamlining or elimination of

lower priority projects. The IT infrastructure consolidation will further reduce infrastructure expenditures for several HHS agencies and should be fully implemented by October 2003.

IMPROVING THE HEALTH AND SAFETY OF OUR NATION

Mr. Chairman, the budget I bring before you today contains many different elements of a single proposal. What binds these fundamental elements together is the desire to improve the lives of the American people. All of our proposals, from building upon the successes of welfare reform to protecting the nation against bioterrorism; from increasing access to healthcare, to strengthening Medicare; all these proposals are put forward with the simple goal of ensuring a safe and healthy America. I know this is a goal we all share, and with your support, we are committed to achieving it.

Senator SPECTER. Thank you, Mr. Secretary.

Our practice is to have 5-minute rounds, and we will adhere to that. Obviously, there will be a number of rounds for you because of the very many issues which are involved here.

SEVERE ACUTE RESPIRATORY SYNDROME

The most immediate concern, among many immediate concerns—it is hard to put anything ahead of bioterrorism today when the 48-hour period for President Bush's ultimatum will expire in just a few hours. But there is grave concern about the respiratory infection which has triggered a global health alert, and in an era where everybody is worried about plots and plans, some speculation has arisen as to whether this virus might have been planted in China to see what the results would be. And there is some grave concern that this could have enormous implications as an infectious disease.

How serious is it, Mr. Secretary, as a potentially infectious disease that could present an enormous health threat around the world?

Secretary THOMPSON. Senator, we are very concerned about it. It started in Guangdong Province, we think, but we are not sure that there is actually a continuation of that. But basically we think that there is a possibility that is where it started. There were 300 cases there. I have met with the Minister of Health here in Washington from China. At the beginning he was not as cooperative as we would like, but subsequently we have been working very closely with China, with the World Health Organization. In fact, almost on a daily basis I——

Senator SPECTER. Mr. Secretary, what are the details? The reports were that they would not cooperate with us. Is that true?

Secretary THOMPSON. That was true at the beginning, Senator, but that has subsequently changed and we are now going into Guangdong Province, as we speak, with CDC people and WHO people.

Senator SPECTER. What was the cause for their initial reluctance to be cooperative?

Secretary THOMPSON. They were in the process of changing their government. They were also reluctant to have outsiders from the United States come in and assist them at the beginning. They thought they had it controlled and did not think they needed any further help. And those were basically the reasons given to me when I talked to the Deputy Minister of Health when he appeared here in Washington about 12 days ago.

Senator SPECTER. Is there realistically potential for a worldwide epidemic from this respiratory ailment?

Secretary THOMPSON. There is that possibility. We are not certain it is a probability, but it is certainly a possibility. It has showed up now in Hong Kong, Bangkok, Singapore, Sweden, possibly in Germany, definitely in Canada. We are investigating approximately 40 cases in the United States. Forty cases were reported. We are looking at 11 cases, but nothing has been confirmed. Two scientists in Germany have indicated from nasal swabs that there is the possibly of the paramyxo virus, but that has not been confirmed by either WHO laboratories or CDC.

Senator SPECTER. If so, what would that mean?

Secretary THOMPSON. It would mean that it would be a virus that we could identify and would have some way then to control and treat it. But so far, we have not been able, Senator Specter, to make an accurate confirmation from CDC if it is even a virus. We think it is, but we are not sure, and what virus it is has not been confirmed. Therefore, until CDC's laboratories confirm it, we do not make any kind of speculations as to what this particular disease is.

Senator SPECTER. To the extent that you can answer this question—and it may be impossible to answer—what causes something like this?

Secretary THOMPSON. We are not sure, Senator. That is one of the questions that we are still trying to find an answer for.

[The information follows:]

SEVERE ACUTE RESPIRATORY SYNDROME

The cause of Severe Acute Respiratory Syndrome (SARS) is not known at this time. Some researchers have reported finding paramyxovirus-like particles in respiratory specimens from a few cases of SARS. Paramyxovirus is a family of viruses that cause respiratory infections and childhood illnesses including measles, mumps, and croup. The Paramyxovirus family also includes a recently identified virus called metapneumovirus. These are preliminary findings and at this time we cannot say for certain that a paramyxovirus is the cause of SARS. Some of the paramyxoviruses that cause respiratory infections are widespread, especially during the winter season, so it is not unexpected to see them in an upper respiratory specimen. Analysis of laboratory specimens to identify a cause for SARS is ongoing both by CDC researchers and by researchers from other countries.

Information currently available about SARS indicates that people who appear to be most at risk are either health care workers taking care of sick people or family members or household contacts of those who are infected with SARS. That pattern of transmission is what would typically be expected in a contagious respiratory or flu-like illness. However, as the investigation continues, we will continue to consider all possibilities.

Senator SPECTER. Well, it is obviously very difficult to answer that kind of a question, but that is on everybody's mind. Is there any possibly, however remote, that this could be a virus planted as part of biological warfare?

Secretary THOMPSON. It is certainly possible, Senator. We think it is very, very doubtful. We think this is some sort of a virus, but we are not even certain of that.

All I can tell you is that the laboratory scientists and technicians and analysts at CDC are working around the clock. We have just received the specimens from Hong Kong late yesterday afternoon. We needed those specimens. We have got the specimens and the autopsy report in from Canada. We are reviewing all of those

things. The scientists are working extremely hard. I meet either in person or by teleconferences with Dr. Gerberding and the staff at CDC on a daily basis, and we will have a conference at 9:30 a.m. tomorrow for an update as to what the scientists were able to analyze over the evening.

But at this point in time, there is nothing new to report to you, Senator, but I will be more than happy, this afternoon, when I get the update to call you and Senator Harkin so that you can let the other members of the committee know what the results are. We will give you up-to-date information on a daily basis from my office as to what is transpiring, but right now we do not know for sure where it really started. We think probably Guangdong Province, but we are not certain. We are not certain if it is a virus, and as soon as we do find answers to those questions, I will give you a call and let you know directly.

Senator SPECTER. Okay.

During your last answer, my red light went on, so I will not ask another question until the next round.

I would note very briefly that in Pittsburgh recently we see efforts made to get reports from doctors and hospitals to try to see if there is any pattern of an illness which might portend of a biological attack, and at a time when there is such anxiety worldwide, to have this suddenly crop up, it is an avenue which needs to be explored.

Then we are going to come back in the next round, as far as I am concerned, to the CDC, a very important agency undergoing enormous renovations with their laboratory facilities and the budget cuts them at a time when they are an agency of importance second to none. But I will await round two.

OPENING STATEMENT OF SENATOR TOM HARKIN

Now my distinguished colleague, Senator Harkin, Democrat of Iowa.

Senator HARKIN. Thank you very much, Mr. Chairman.

Mr. Secretary, thank you very much for your great leadership at the Department on so many areas.

First, on the budget end, I just want to commend you for your leadership in putting in the systems change grants. We have talked about that in the past. You have taken great leadership on that. This is one where it is going to make a real difference in States in getting people out of institutions and getting them in the community. So thank you very much for that and for including these grants in your budget.

Again, I also want to compliment you on your great emphasis on prevention in the budget and what you are doing on preventative health care. I know you personally spearheaded this new emphasis. I wish we had more dollars in there; I am sure you do too.

But I would just make note that on another committee on which I sit, the Agriculture Committee, this year we are reauthorizing the school lunch, school breakfast WIC program, summer feeding program. I hope there is a good cross-fertilization between your Department and Agriculture on some of these issues. There is a blending here, and we need, I think, to start promoting, as you said in your own budget proposal, healthier lifestyles, cutting down on

childhood obesity, getting kids more exercise programs, getting them learning how to eat right in the beginning. So I guess I am just making a plea for you to help us as much as you can in another Department——

Secretary THOMPSON. I would love to.

Senator HARKIN [continuing]. Because I think this is a merge here and we need your help on these matters as we move ahead.

After all those accolades, I will say I am disappointed in the 2.5 percent increase for NIH. I do not know what we are going to do about that, but that really is not acceptable. We have got to have a bigger increase in NIH than that 2.5 percent increase.

HEAD START

Lastly, again on Head Start, Mr. Secretary, you have been a great leader in Head Start. I know your devotion to the program. I know you have been very supportive of it. For years now, I think for the 18, 19 years I have been on this committee and on the authorizing committee, there have been at various times proposals to take Head Start and move it into Education. People think that this is an education program and we are going to teach kids how to read. Well, that is a part of Head Start.

But as you have pointed out in your own document statement, these kids come from low-income families. They do not have the kind of family support. They do not even have the health support. Their health matters are usually worse. Their living conditions and socialization skills are worse. Head Start is something that reaches into all these areas. So rather than trying to move this to the Department of Education, I think we need to put more emphasis on Early Head Start, the 0 to 3, and getting more into that area.

So I say to you as a great friend and an admirer of yours, Mr. Secretary, please go back and tell your boss and the other people around that there are a number of us here who are not going to let it be transferred to the Department of Education. It ain't gonna happen.

Secretary THOMPSON. I have already said that, Senator.

Senator HARKIN. Okay, well, then tell him you have got backing up here. It is not going to happen. So we are on your side on that, and we will do everything we can to support your budget in that area.

CENTERS FOR DISEASE CONTROL AND PREVENTION INITIATIVE

Lastly, my time is about to run out. I made a statement, but I guess my question would be getting back to CDC, the Centers for Disease Control. You have that new $100 million prevention initiative at CDC. Again, I just hope that we can put a lot of emphasis on that and that we can focus some more attention on building up CDC. We have done NIH. We got it doubled. We need to keep it going. The 2.5 percent is too low.

But, Mr. Secretary, I just need your thoughts on CDC and where we are headed this year in terms of getting them up to speed and getting the kind of budget that they need both for the prevention, which you are aimed at, which is good, but also for the public health aspect that we need in America to build up our public health infrastructure that I think—well, I do not know if you agree

or not—I think really went downhill over the last 40 years, and we need to build it up again. So just your thoughts on that.

Secretary THOMPSON. Thank you so very much. Can I just quickly go through a lot of the points you raise?

Senator HARKIN. Sure.

Secretary THOMPSON. First, on the Freedom Initiative and on the grants initiative, thank you for your leadership. It is the right thing to do to keep people in their own home, and I am fully behind it, enthusiastic, glad we put the extra money in because it is the right thing to do.

In regards to prevention, $152 billion a year spent on tobacco-related illnesses. 400,000 people die. $132 billion a year on diabetes. Seventeen million Americans are diabetic. Sixteen million are prediabetic, and 200,000 people die a year. We have done an exhaustive study in which 60 percent can be prevented if, in fact, we walk 30 minutes a day and lose 10 to 15 pounds.

Senator HARKIN. Can I interrupt you right there, Mr. Secretary?

Secretary THOMPSON. Sure.

Senator HARKIN. A recent study showed that 80 percent of elementary school kids in America do not even get 1 hour of PE a week at the schools—80 percent.

Secretary THOMPSON. It is not the right thing to do. And we have got to get people out—$117 billion on obesity and 300,000 people die. Senator, we have to do it. Ninty-five percent of the money in Medicare goes to waiting for people to get sick and then getting them well, and only 5 percent on preventative health. We need to put more money into it.

NIH, granted it is 2.5 percent. But the actual research dollars will be $1.9 billion, or a 7.5 percent increase because we put more money in fiscal year 2003 into buildings in one-time costs, such as $250 million in anthrax expenditures, plus the extramural capital expenditures. So actually we are going to have a 7.5 percent increase in the research. There will be more research grant dollars than ever before.

On CDC, in regards to preventative health and on State health, you are absolutely correct. We let it go downhill.

But thanks to your leadership and that of Senator Specter and this committee on a bipartisan basis in Congress, we put $1 billion last year in fiscal year 2002 in building up the State health departments. And I want to tell you one of my concerns is the States have only drawn down 19 percent of that money. We got it out there and the States have only drawn down—we got an additional $1,418,000,000 to send out this year, and we are in the process of sending it out. So if you could help me get the State of Iowa to draw more of their money down and use it, it would be very helpful. We need to do it. Plus, we are asking an additional $1.5 billion for fiscal year 2004 to do it. We have the greatest opportunity, Senator, to be able to build up local State health departments the way you envision it, the way I envision it, than we have ever had before. The money is there. The money is out the door and it has been allocated. It just has not been drawn down by the States.

Senator HARKIN. Fascinating. Thank you, Mr. Secretary. We will look into that.

Senator SPECTER. Senator Craig.

OPENING STATEMENT OF SENATOR LARRY CRAIG

Senator CRAIG. Well, Mr. Chairman, thank you very much.
Mr. Secretary, great to have you with us this morning.
Secretary THOMPSON. Thank you, Senator.

COMMUNITY HEALTH CENTERS

Senator CRAIG. I have some comments and you may want to react to them much like Senator Harkin, but let me commend you first for your continued support of community health centers. The budget proposal takes another positive step toward improving the health care in rural America. Most of my State still gets the definition of being rural. And the inclusion of $122 million to provide primary and preventative health services to nearly 14 million individuals is a great advance, I think, for our Nation's health centers.

NATIONAL HEALTH SERVICE CORPS

In addition, your focus on the National Health Service Corps I think would provide much needed scholarship and loan assistance to additional health care providers in underserved and rural areas.

AGING

I have a fun experience and a unique opportunity now, serving as the chairman of the Special Committee on Aging. I have got a great staff. We are doing a lot of exploratory overview of the aging of America, Mr. Secretary. I must tell you that it is, without question, time to modernize and improve Medicare. All of us understand that. The prescription drug item in it is going to be important if we can work out our differences.

CHRONIC ILLNESS

But you have talked about the way health care is delivered. We have got some excellent pilot programs going on at CMS as it relates to managing chronic illnesses. We could literally take all of those who have that situation, pay for their full health care if they would simply adhere to the protocols, and we would save billions and billions of dollars a year in health care costs and certainly in their ability to conduct and live in society.

OBESITY

But the thing that fascinates me most in this process—and, Senator Harkin was talking about the growing epidemic of obesity in this country. We have got 60,000-plus centenarians in our country today. That is 100 years old or older. With current trends, we are going to be over 1 million in 60 years. And if we find the cure for cancer—and we know we are certainly on the threshold of major breakthroughs—that number skyrockets. Thank goodness, a positive sign in the lives of Americans.

At the same time, those people are going to be able to live a great deal better if they exercise and if they have good nutritional advice and understand the value of nutrition. We have held several hearings in that area today. It is dramatic what happens in the senior community as it relates to the cost of health care when they

simply exercise and eat right. The cost goes down dramatically and they live longer and they are much healthier.

While we are not teaching our kids to exercise anymore, we know that most people do exercise better, at least if they are learning to, in groups. In certainly our seniors we are finding that to be the case also. They will tend to exercise if they can exercise together. That is some work we are going to spend a good deal more time with. But it is something that, clearly, as we look at our health care delivery systems, we ought to be a lot more interested in preventative than maintenance. If we can get at that, the costs involved will be dramatic.

I am pleased to see the President's Disease Preventative Initiative and the support that is going on there. But it is obvious to me that we have got to modernize our health care delivery system or that part of it that we are participating in—it is lagging by about 30 years, and it makes good sense to get us active in promoting all of these things.

I think your budget certainly goes in that direction. It is going to be a tight budget year. We all understand that. There is a good deal more we would like to do, but this is probably a year when we will not be able to do all we would want to do. I am quite sure Americans will agree if we are in a time of war and we have certain responsibilities there, there is going to have to be an understanding of allocation.

But I thank you very much, and I am pleased to see the direction we are headed in.

Secretary THOMPSON. Senator Craig, thank you so very much for your comments. I appreciate them tremendously and I can only say that I want to work with you on all of the subjects. Community health centers, absolutely doing an awesome job. They are serving the underinsured and the uninsured and a lot of minorities. We are expanding them thanks to the cooperation on a bipartisan basis. We are very appreciative of that support.

The National Health Service Corps. Very important to get doctors graduated, get them out into underserved areas like your State and my State and the States of the members on this committee. I want to work with you on that. It is something that we need to do more of.

Medicare-strengthening and prescription drug coverage. Absolutely vital this year. You have certainly heard about the trustees' report. Certainly I was very concerned when we met this past Monday. Medicare is going to stop having a surplus in the year 2013, 3 years sooner than it was before. This is going to cause all kinds of problems. It will be absolutely broke by the year 2026, 4 years earlier than it was estimated last year. So it is accelerating, and that means that at the present time, 2 percent of the dollars that go into the budget come from loans from Social Security and Medicare. It will no longer happen after fiscal year 2009. A big concern of the Congress and of mine.

Medicaid needs to be improved and strengthened, and that is what we are trying to do with the new Medicaid proposal.

In regards to the individuals that are living longer, there is no question about that. The demographics show that we must start

addressing that issue—and I do not think we have done a very good job in the past.

Senator CRAIG. I agree.

Secretary THOMPSON. And I thank you so very much for taking the leadership in this area.

We have got to find ways in which we can get some tax credits for people to purchase long-term insurance. We have to get more people involved. We have to figure out a way to get tax credits, I think, for individuals who start leading healthier lifestyles. It is going to be very difficult and complex, but it is something that I think we should do.

I am setting up a summit with the National Institutes of Health and the University of North Carolina Medical School in which we are going to have a summit of health insurance companies, of fast food industries and businesses, as well as individual organizations around the America to talk about preventative health and how we might be able to work together in America to start changing lifestyles. That is why the $125 million is the request in there from my Department, from me personally because I really believe that this is something we have to do.

Unless we start exercising, unless we start eating properly and losing some weight, we are going to continue to cause a tremendous rupture in the health care delivery system because $152 billion a year on tobacco-related illnesses, $132 billion on diabetes, $117 billion on obesity, all of these can be changed dramatically by watching what we eat and exercising. That is why the $125 million is going to be put out there.

We are going to try and declare certain cities "healthy cities" and have them vie for it. They have to show a reduction in asthma and diabetes. They have to show that they are improving their walking trails for families in their communities. I think it is going to be a very well thought and well received program. I have talked to the League of Cities across America. They have been very supportive of it because they can see what it would mean to their city if they are designated as a healthy city.

I think that these are the kinds of things that we can work together on a bipartisan basis and really improve the quality of health, hold down on dollar amounts because we are spending so much on waiting for people to get sick and then trying to get them well when we could spend a lot less and keep people healthier and lead a better quality of life for all Americans.

So I thank you and want to work with you on these particular subjects, and we will, hopefully, be able to start programs that are really going to accomplish these objectives.

Senator CRAIG. Well, Mr. Secretary, thank you for those comments. I find it ironic, as we have worked over the last several decades to take fat out of our diet, that we created an obesity epidemic.

Secretary THOMPSON. We really have.

Senator CRAIG. I think we better revisit our nutritional patterns.

Thank you.

Secretary THOMPSON. Thank you very much. I put the whole Department of Health and Human Services on a diet and I want to tell you that we are doing well.

Senator CRAIG. Good.
Senator SPECTER. Senator Landrieu.

OPENING STATEMENT OF SENATOR MARY L. LANDRIEU

Senator LANDRIEU. Thank you, Mr. Chairman.

Let me just begin by welcoming you, Mr. Secretary, and I look forward to working with you on many of the issues that we have worked well together on in the past and look forward to some more progress in adoption and foster care and Head Start, early childhood education, et cetera.

TAX CUTS

But just a couple of comments. I agree with the Senator from Idaho about the sacrifices that we need to make at this particular time with the war looming and with great challenges on the home front. But I would hope that those sacrifices could be equally shared and not borne disproportionately by the poor children of this country and by the vulnerable elderly. So when sacrifices have to be made, I hope perhaps some tax cuts for certain segments could be postponed or put on hold while we make sure that we are covering the essential services to poor children and their families so that the sacrifices made do not fall disproportionately on just those in uniform and their families and the poor children and the vulnerable seniors. So that is going to be a major debate as we frame the budget that you are able to operate.

Second, with the modest increase that you are given, you have got quite a challenge before you in terms of meeting the challenges that you have just stated in answering many of the questions: medical, Medicare, the obesity issue, substance abuse, the number of children in foster care, the health care system that you could claim in some ways is in a crisis situation because we are not particularly geared right now to handle just the regular medical challenges of this Nation, but the bioterrorism challenges, which of course is homeland defense, but nonetheless important.

FOSTER CARE

But let me, having just opened with that, ask you a couple of questions about your budget. I noticed with great interest your comments, although they were brief in the budget, about an "alternative funding system for foster care." Would you just take a moment to maybe elaborate on some of your ideas regarding more flexibility in the foster care system in that we are spending I think somewhere, including the State portion, about $8 billion trying to—I do not know how you describe what we are trying to do. I guess we are trying to keep families together, but when they cannot be kept together, promote adoption. In the meanwhile, we support the sort of temporary foster care system that in my mind has gotten quite expensive.

I think that there would be ways to actually do a better job servicing our families, saving children, promoting adoption for maybe less money if we could rethink the way this funding stream is put together. So could you just give a brief—and I want to just give a

minute to this if you could about what some of your thoughts might be.

Secretary THOMPSON. I certainly will try, Senator Landrieu.

First off, let me thank you for your leadership in this area because you have definitely been a leader on adoption and foster care, and it is well recognized. And I want to work with you. Senator Clinton and Congressman——

Senator LANDRIEU. DeLay.

Secretary THOMPSON [continuing]. Tom DeLay have contacted me and want to work with me on this, and I would appreciate you also working with me on it.

Right now, as you probably know, the foster care system is somewhat arcane in that you can only use the Federal 4(e) dollars in foster care for children who are defined under the old AFDC formula, which was eliminated in 1996. So you have to go back and compute the children under that formula, which is no longer in existence, and you can only use the Federal dollars for that and then you can only use the Federal dollars after the family has broken up or has caused problems and the child is removed and placed in a temporary foster home.

We think we should be able to spend the money, hopefully, at the preventive stage. I am big on this prevention because I think that is where we need to go as a Government, is to start preventing things before they happen. If we could use some of the Federal dollars in a preventative stage, on a voluntary basis, I think we could cause a lot better outcome. I think the families could stay together. The children could stay in the families instead of being removed and going into the foster care system. That is the thrust of our proposal and that is the alternative funding, is to go into the preventative stage on a voluntary basis. It would not be mandatory. It would be a voluntary thing.

We are hopeful that we are going to be able to get bipartisan support on this. It appears that the Governors are very supportive so far, and it appears that we are getting bipartisan support. I would certainly solicit your support in this as well.

Senator LANDRIEU. I look forward to working with you. I have got one more question, but I want to just encourage you along that line because with the new legislation that has been supported on a bipartisan basis to really promote unification where possible, but then move quickly to adoption when it is not, and focus also on the preventive aspects, which is substance abuse treatment for some of these families that, if treated, could potentially continue to raise their children and do a good job. So I really encourage you and look forward to working with you.

HEAD START

But my second point would be on Head Start. I would say to the chairman and the ranking member while there are disagreements right now or different views, I should say, about this program, I hope that we would not establish victory for either side as to whether it stays in the Department of Education or just stays in the Department of Health and Human Services. That should not be what we decide is victory. What victory should be is having an early childhood education program in this Nation that is up to the

task of getting children basically ready to learn when they hit that kindergarten door.

That is going to take a combination of efforts, Mr. Secretary, as you know, combining the resources of the cities, the States, of the Department of Health and Human Services, and the Department of Education. So I would like to really think about using this not to create a fight between agencies, but use it as an opportunity to really strengthen a signature program that could have a dramatic impact, Mr. Secretary, if we do it right, on all the things that you outlined and could be a tremendous legacy for you and for your administration to get that in place.

So I look forward to working with you and the members of this committee to fund the reform efforts that you put down. Thank you.

Secretary THOMPSON. Senator Landrieu, thank you so very much for your comments, but thank you so very much for your willingness to help on this Heat Start. I could not agree more enthusiastically with what you want to have as the outcome. If we can develop a better program—that is why you are in Government. That is why I am in the administration. We should work for that. I am confident that Secretary Paige and I will work on a collaborative basis with you. Any suggestions you might have on how to improve the program I will take very seriously I know, and I know Secretary Paige will.

I think we can develop a much better program. What we are trying to do is allowing for the States to be able to integrate their early childhood dollars, because I think really there is a disconnect there. And I would like to be able, on a voluntary basis, to allow Governors to have more involvement in the early childhood stages.

Second, I would like to put a lot more emphasis on the earliest childhood, the 0 to 3. That is where we really need to put some more emphasis. And I know you agree with that, and I thank you so very much.

OPENING STATEMENT OF SENATOR HERB KOHL

Senator SPECTER. Senator Kohl, your timing is impeccable. You arrived just in time for your round of questions.

ABUSE AND NEGLECT IN LONG-TERM CARE FACILITIES

Senator KOHL. Thank you, Senator Specter.

Welcome, Mr. Secretary. Mr. Secretary, at last year's hearing we talked about how important it is to make sure that State survey agencies and ombudsmen have enough funding so they can inspect nursing homes and other long-term care facilities, also to investigate complaints of abuse and neglect.

As you know, every year I have worked hard to increase funding for these programs, and so I was disappointed to see that the President's budget for this year actually cut survey funding by $6 million from 2003 levels that we just enacted, and it flat-lines the ombudsmen funding.

I cannot imagine how we can cut these programs when abuse and neglect complaints jumped by nearly 14 percent least year. So to me it is clear that we need an increase and certainly not a de-

crease in our efforts to make sure that all patients in long-term care are safe.

So I ask you, how can we expect States and ombudsmen to carry out these critical duties if we cut their funding, and can we do something about it?

Secretary THOMPSON. Senator Kohl, thank you so very much and thank you for your leadership in this area. As you know, when you and I worked together in the State of Wisconsin, we got a mandatory proposal through, and I think it is probably one of the best laws in the country in regards to that. I know it was signed into law, and I know you were very supportive of that.

Senator KOHL. Very much so.

Secretary THOMPSON. You know that I agree with you.

Second, it was not a cut, when we introduced it, Senator. The problem was when we introduced the budget, the Congress had not passed the fiscal year 2003 appropriation, and you were very successful in getting additional money put in. So our budget was in when the fiscal year 2003 budget was in, which increased it by $6 million, which we had level funded it. We had not cut it. We had level-funded it from the year before.

Third, it was a tough budget. This is one of the items I had appealed, but I lost on the appeal to OMB. I understand your concern. I just want to work with you to build the best surveillance as we possibly can.

As you probably know, we have started nursing home quality standards, and we started an experimental program with six States. Now it is national. And it is working out very well. The nursing home industry has bought into it, and we are now on the CMS web page. We are able to allow people to look at the comparisons of nursing homes within their State so that they can find out which nursing homes are doing the best job in various areas. This is also something I am sure you would approve of. These are the things that we are trying to do to improve the quality in our nursing homes for our senior citizens.

Senator KOHL. I know how much you care about the issue and I know that we will be able to continue working on it.

One other question in this area. As you know, Mr. Secretary, over the years Congress has held many hearings on abuse in nursing homes and we heard stories from people about patients being beaten, raped, and even killed by employees who are supposed to be caring for them. We know that the vast majority of nursing home workers do a very good job, but as we know, it only takes a few to corrupt a whole system.

I have introduced legislation to create a national registry of abusive workers and require FBI criminal background checks before hiring. The bill is supported by patient advocates, as well as the nursing home industry. As we debate Medicare reform this year, we will hear a lot of ideas about what exactly reform means. But it seems to me at the very least one of the most important reforms we should pass is to ensure the basic safety of those who are already in nursing homes and already covered by Medicare. Nursing homes receive more than $11 billion in Medicare funding in 2001, and I believe we have an obligation to make sure that these dollars are well spent.

So will the administration support legislation to get a national registry of potential nursing home employees and will the administration, will you, work with me and others to get it passed this year?

Secretary THOMPSON. As you know, I worked with you when we got it passed in State of Wisconsin, and I will continue to work with you, Senator. I think it is the right thing and I hope that we can get it done.

Senator KOHL. I thank you so much. It is good to see you.

Secretary THOMPSON. It is always a pleasure.

Are the Bucks going to make it?

Senator KOHL. It is going to be tough.

Secretary THOMPSON. Well, let us do a little bit more in that area too, Senator.

Senator KOHL. Well, I will but I want to assure you, Governor, it is not because I am not paying them enough.

Secretary THOMPSON. I know that, Senator. Let us just hope they make it to the playoffs.

Senator KOHL. All right.

Senator SPECTER. Senator Gregg, like Senator Kohl, your timing is impeccable. You arrived just in time for your round of questioning.

OPENING STATEMENT OF SENATOR JUDD GREGG

Senator GREGG. Well, I appreciate that. Unfortunately, I have to head off to carry the Secretary's water at the markup that I am starting on bioshield, respite care, and a variety of other things he sent to us to do. So my only question would be to the Secretary—well, I am going to reserve my questions because it will take too long to answer, and I would have to leave in the middle of the answer. But it is a pleasure to see the Secretary here and I look forward to continuing to work with him.

Secretary THOMPSON. Thank you, Senator Gregg, for your tremendous support on the smallpox and bioshield initiatives. And thank you for coming over and viewing the Department's new communications center. I extended that invitation to all members. I would like to have them come over because I think you would attest that it is one of the most modern in the Government.

Senator GREGG. An extremely impressive facility. I think it could be of value to every Senator to have a chance to look at it and see the resources there.

CENTERS FOR DISEASE CONTROL AND PREVENTION

Senator SPECTER. Secretary Thompson, on my first round I was focused on what the CDC was doing on the China virus, and the very broad responsibilities which CDC has on bioterrorism. But I note that CDC has been cut by $160 million on their overall budget and $152 million on CDC's buildings and facilities.

Starting first with the $160 million cut, is that wise, appropriate in the context where we consistently call on the CDC to do more, illustrated by the current Chinese virus?

Secretary THOMPSON. The CDC budget, Senator, as you know, is very important to you. It is very important to me. It is very impor-

tant to our country. During the process of give and take with OMB, you are given so much money. You try and do the best job possible.

In regards to the building program, I requested $250 million, which was sort of the glide path in order to get——

Senator SPECTER. You are talking on the building program now?

Secretary THOMPSON. Yes.

Senator SPECTER. I am about to come to that. The building program has been cut by $152 million.

Secretary THOMPSON. $152 million out of the $250 million.

Senator SPECTER. The facilities had been in a longstanding state of disrepair which had not been focused on by your predecessors until members of this committee went down and took a look. You know that story.

Secretary THOMPSON. I know it very well.

Senator SPECTER. We had an emergency appropriation that year, about 3 years ago, of $170 million, and we added $250 million and $250 million. We have had very vociferous complaints from the community which is really up in arms. When I was there, I saw distinguished scientists with desks in the halls—you know about that—and very important chemical substances unprotected, unsafeguarded. When was the last time you saw the CDC, Mr. Secretary?

Secretary THOMPSON. I go to the CDC about every 6 months. I am going down there again——

Senator SPECTER. Well, how was it when you saw it last? Are the conditions still pretty bad?

Secretary THOMPSON. Conditions are improving. We are making a lot of progress. We still have a long ways to go.

Senator SPECTER. They are improving, but are they still pretty bad?

Secretary THOMPSON. The laboratories should be finished up this year, and that was our highest concern. Our laboratories, as well as for the security of them. That has come along very nicely, but there are some other buildings.

The problem is we have three campuses, and we have 24 other buildings that we are renting around the City of Atlanta. It really causes a disconnect. There is not the synergism that we could have if we could relocate those 24 buildings on campus and have the building program go.

I understand your position, Senator. Oz Nelson and Bernie Marcus have been leaders down there, and I think they met with you yesterday. They have talked to me. I talk to them on a very regular basis. We are trying to get $250 million which was the glide path——

Senator SPECTER. Well, I hope you talk to them as regularly as they call me.

Secretary THOMPSON. Well, I am sure they probably call you more.

Senator SPECTER. I'm going to give WATS line with those folks.

But we ask them to do so much.

My time is close to expiring, and I want to stick to the time limits here.

NATIONAL INSTITUTES OF HEALTH FUNDING

CDC is tied very closely with the NIH funding, and the NIH funding—you know what this subcommittee has done. When you present a budget like this to us, Mr. Secretary, you really leave us in a position of adding to the CDC and adding to the NIH and taking away from other programs. And I know your problems with OMB, but I suggest to you there has to be a tougher level of advocacy on these lines.

The subcommittee would like to know how many grants have been awarded by NIH, what will happen with the flow of grants when the increase is only a figure of $673 million. I will ask as the final question before my red light goes on, why does the administration request only $673 million for NIH when last year it was $3.7 billion?

Secretary THOMPSON. First off, Senator, I do not know how I could be a stronger advocate than what I have been in the past.

Senator SPECTER. Well, you can take over OMB, Mr. Secretary.

Secretary THOMPSON. Well, I suppose I could, but I was not asked to do that, Senator, and I do not think they are going to ask me to do it either.

I am a strong advocate. I am passionate about it. And I thank you for you passion because it has been yours and Senator Harkin's and members' of this committee that have been able to do it.

In regards to NIH funding, it is a 2.5 percent increase over what the fiscal year 2003 request was, but——

Senator SPECTER. How do you figure a 2.5 percent increase? Do you have a different slide rule than I do?

Secretary THOMPSON. No, I do not. Subsequent to the introduction of our budget, Congress passed the fiscal year 2003 appropriation bill which increased the amount of money over and above what we had requested. Therefore, instead of a 2.6, it was about a 1.6 percent increase over what you appropriated. But what we put in over what was in the fiscal year 2002, it is a 2.6 percent increase. That is the difference.

In regards to that, there was $250 million put in for the purchase of anthrax which is no longer there. That has been purchased. There was a one-time capital cost in the NIH budget for building laboratories at Fort Detrick and also on the campus, and also the remodeling of a laboratory in Montana. Those things have been done. There was approximately $375 million put in for capital improvements on campuses, on universities for bioterrorism laboratory advancements, as well as other things. Those were one-time costs. When they are taken out, you add that back into the research. Those one-time dollars will no longer be going for the expenditure of anthrax and for capital costs. They will be going back into research. So the total amount of money going for research over last year will be $1.9 billion, or a 7.5 percent increase, which will allow us to send out more grants and more dollars than ever before. And that is just how it works out, Senator.

Senator SPECTER. Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman.

Mr. Secretary, I am shifting a little bit here. I just again wanted to focus on this new Freedom Initiative, the disability grants, which I compliment you for moving ahead on that.

There are enough people who want to ask questions. Why do I not write you a letter on this and discuss this with you? I am concerned about what happens after the first year. You have got these grants in there for the first year. What happens after that? I mean, they cannot just drop off a cliff someplace. And there is a match there for that first year. Then after that, we do not know. So I am greatly concerned that States may go into this, and then after the first year, they have nothing. And I do not know what the plan is for that. But maybe I should write you. Maybe you could respond to me on that basis.

[The information follows:]

NEW FREEDOM INITIATIVE

There are several components to the New Freedom Initiative proposal, the following are items with fiscal impact in the fiscal year 2004 and beyond (many of these demonstrations were also proposed in the President's fiscal year 2003 Budget):

—*Medicaid Spousal Exemption*.—$95 million over five years, with $16 million proposed for fiscal year 2004. This proposal would give States the option to continue Medicaid eligibility for spouses of disabled individuals who return to work. Under current law, individuals with disabilities might be discouraged from returning to work because the income they earn could jeopardize their spouse's Medicaid eligibility. This proposal would extend to the spouse the same Medicaid coverage protection now offered to the disabled worker.

—*New Freedom Initiative Demonstrations*.—$220 million over 5 years, with $11 million proposed for fiscal year 2004. This initiative would fund four demonstrations that promote home and community-based care alternatives. Two of the demonstrations provide respite care services for adults and substantially disabled children. Another demonstration provides community-based care alternatives for children who are currently residing in psychiatric residential treatment facilities. The President proposed these demonstrations for fiscal year 2003. Also included is $3 million in discretionary spending for the CMS Research and Demonstrations Budget that will fund the Direct Service Worker National Demonstration.

—*"Money Follows the Individual" Rebalancing Demonstration*.—$1.75 billion over 5 years, with $350 million proposed for fiscal year 2004. This 5-year demonstration would finance Medicaid services for individuals who transition from institutions to the community. Federal grant funds would pay the full cost of home and community-based waiver services for 1 year, after which the participating States would agree to continue care at the regular Medicaid matching rate. This demonstration would also provide incentives to States for increased use of home and community-based services and would help provide information on costs of different approaches.

The fiscal year 2004 budget will also include $40 million for "Systems Change Grants" to support States in their planning to create new systems to support people with disabilities in the community instead of in institutions.

Secretary THOMPSON. Senator, I really think that the evidence is going to show that this is the right thing to do. I think that you have recognized that for many years and have been pushing for this thing. It is something I did when I was in Wisconsin. I moved people from nursing homes and left them in their own homes.

Senator HARKIN. I am aware of that.

Secretary THOMPSON. Also, for the disabled community, we did the same thing. It is so much better—a quality of life issue—that I just do not think, once you start down this path, that you would ever be able to stop it. I think the advocates, I think the Senators like you, Senator Harkin, and I think the administration have made a commitment, and I think they have made a commitment

to the community and I think we are going to stand by that. As long as I am here, I know I am going to be pushing for it, and I know I am going to have your support in order to accomplish that.

Senator HARKIN. Thank you, Mr. Secretary.

Senator SPECTER. Senator Craig.

Senator CRAIG. Mr. Chairman, I have no further questions.

Senator SPECTER. Senator Landrieu.

SUBSTANCE ABUSE

Senator LANDRIEU. Yes. Mr. Secretary, let me just follow up with our substance abuse focus, if we could, because as you know, the record speaks clearly about the reason that I think maybe 70 to 80 percent of children in foster care are there because a parent or both parents have a serious substance abuse problem. I do not have to share with you the statistics about our prisons being full of people who have substance abuse problems and for whatever reason—not that those reasons are excused—turn to a life of crime, et cetera. My point being that since we spend I think $30,000 or $40,000 per year to incarcerate someone, it would seem to me that one of the smartest investments we could make as a nation is trying to find and continuing to pursue, even though it is difficult, a very effective remedy or program for substance abuse.

Your budget here, the block grant that we provide to our States, provides treatment services to 400,000 people. Do we know how many people in the country are suffering from substance abuse that could potentially be helped by a block grant like this? Do we have a figure that we are shooting for?

Secretary THOMPSON. I am sure we do, but I do not have it at the tip of my——

Senator LANDRIEU. Could anyone on your staff share with us? Do we know what the universe is that we are dealing with?

Secretary THOMPSON. I know we have that information. I will get it for you, Senator Landrieu.

Senator LANDRIEU. Because I think it is huge.

Secretary THOMPSON. It is.

Senator LANDRIEU. I think it is millions and millions and millions of people that are suffering from substance abuse. And I point out to the committee and to the chairman that the block grant only provides for services for 400,000 people in the country. So we are just woefully short in that line item. So if you could provide for me the universe that we have at least identified as the numbers of people who have serious substance abuse—you know, chronic—I would just ask.

Secretary THOMPSON. We will get that information for you.

[The information follows:]

PRESIDENT'S DRUG TREATMENT INITIATIVE

In fiscal year 2004, we are requesting a total of $2.6 billion for the President's Drug Treatment Initiative to provide drug treatment services to approximately to 725,000 individuals, an increase of 135,000 individuals over fiscal year 2003. We are requesting an increase of $31 million for the Substance Abuse Prevention and Treatment Block Grant and $200 million for a new voucher program, Access to Recovery, to increase treatment options and expand access to services to 100,000 individuals, including services provided by faith-based organizations.

We believe that these increases in substance abuse treatment will help us reach those people who need treatment. According to the 2001 National Household Survey

on Drug Abuse, 5 million people needed but did not receive treatment in 2001. Of this 5 million people, an estimated 377,000 reported that they felt they needed treatment for their drug problem. This includes an estimated 101,000 who reported that they made an effort but were unable to get treatment and 276,000 who reported making no effort to get treatment.

Senator LANDRIEU. And then try to provide me, if you would, in your opinion what are the one or two or three most effective either statewide or regional programs. And by effective, I mean a record, an objective record, of people entering the program with problems, exiting the program cured, which is I know very difficult. Because if we could identify some of those effective programs, I would like to work with you on moving some of the money out of corrections and out of foster care and into drug abuse treatment and prevention so as to save this Government a tremendous amount of money and, needless to say, a lot of heartache in the process. So if you could provide that for me.

[The information follows:]

SUBSTANCE ABUSE PROGRAMS

Numerous studies have shown substance abuse treatment to be effective in reducing substance use, crime, and infectious diseases, while increasing employment and social functioning. For example, in Louisiana, the Department of Health and Hospitals, Office for Addictive Disorders administers substance abuse prevention and treatment services in 10 regions throughout the State. The Office for Addictive Disorders requires substance abuse treatment programs to screen, assess, and place individuals in need of substance abuse treatment using standardized assessment instruments such as The Diagnostic and Statistical Manual (DSM–IV–R) of Mental Disorders, the Addiction Severity Index, 5th Edition, and the Patient Placement Criteria for the Treatment of Substance Related Disorders, 2nd Edition Revised. The appropriate assessment and placement of individuals in need of substance abuse treatment is critically important to the desired treatment outcomes of achieving and maintaining abstinence and recovery.

The Office for Addictive Disorders has identified two exemplary programs:

1. Rainbow Social Detoxification, Alexandria, Louisiana (Region VI)

The program reported: 98.5 percent occupancy rate for the last calendar year; 63 percent of clients admitted showed improvement in the first two quarters of the current fiscal year according to exit data; and 78 percent of the clients completed the treatment program in the last fiscal year.

2. Infinity Women With Dependent Residential Program, New Orleans, Louisiana (Region I)

This is a collaborative effort between the Office for Addictive Disorders and the Office of Family Support utilizing TANF funding to provide substance abuse treatment to women and their children.

Of the women who completed treatment: (1) 100 percent are enrolled in school or employed at 1-month follow-up post discharge; (2) 100 percent reported a reduction in drug/alcohol usage at 1-month follow-up post discharge; 92 percent of the children ages 0–5 demonstrated improvement in their developmental assessments from admission to discharge; and 53 percent of school aged children demonstrated improved academic performance admission to discharge.

Additionally, the following programs have reported promising treatment outcomes for their respective targeted population in need of substance abuse treatment.

City of Boise Collaborative Methamphetamine Treatment Services Project, Boise, Idaho

Target population: The target population for this SAMHSA-funded project is adults ages 18 and up, methamphetamine users, male and female, and their families in Boise and the surrounding community of Ada County. The project will serve between 50–75 clients per year.

Outcomes: The project is estimating that a minimum of 75 percent of all clients admitted will graduate from the treatment program with client outcomes similar to those of other comparable Matrix model programs in relation to being drug free, employed, or engaged in productive activity; living in a permanent place within the community; and having little or no involvement with the criminal justice system. After fiscal year 2003, the project will determine the program's impact on the fol-

lowing: (a) decreased crime, arrest, convictions, and incarcerations; (b) decreased emergency room/medical/hospital visits; (c) decreased foster care placements; and (d) reduced health and social costs from associated drug use.

The Pinal Hispanic Council Adolescent Treatment Project, Eloy, Arizona

Target population: The target population for this Substance Abuse Prevention and Treatment block grant-funded project are Chicano, American Indian, and African American adolescent males and females between the ages of 10–18.

Outcomes: Pinal Hispanic Council receives Federal and State funds and is a multiethnic, adolescent treatment improvement project which provides comprehensive substance abuse treatment services to a tri-county rural community in southern Arizona. Their main office, located in Eloy, is "Centro de Ayuda" (Help Center) and two satellite offices, "Centro de Unidad" (Unity Center) are located in Coolidge and Casa Grande. The program receives the majority of its patients from the various public schools, families, and the juvenile justice department. The drugs of choice are primarily alcohol, methamphetamine, inhalants, marijuana, and crack cocaine. A home-based approach to treatment is used and a bilingual multi-cultural staff ensures cultural sensitivity. Approximately 85 percent of the 48 clients completed treatment in the last fiscal year. This program is a model for both delivering services in a rural community and in coalition building in a rural community.

Secretary THOMPSON. Senator, thank you so very much. You know we have also put in this new program for mentoring and counseling children of prisoners because they are going to get out and we want to be able to try to get them reintegrated back in the family if it is possible and if there is not going to be any kind of spousal abuse or anything like this. This is a program that we think will be very effective. But there are many demonstration programs out there that we would certainly like to work with you on and see if we could make it a national program.

Senator LANDRIEU. And the reason that I bring that up, is because I think the public has a sense that there are no cures or that they are so difficult, people just throw their hands up and say what is the use of funding it, it does not work. So what we have to do is give people hope that there are, in fact, effective programs that do work, that can be put into place, and that we can really make a serious advancement here on this particular subject. So, thank you.

One other thing for the record. If you could supply me with the grants that either universities or scientists, doctors, physicians, the medical infrastructure in Louisiana has received from NIH, I would appreciate that. I know that there are records to that effect, and if your staff could get that for me, that would be very helpful.

Secretary THOMPSON. For all the universities——

Senator LANDRIEU. For all universities in Louisiana in the last 3 years.

Secretary THOMPSON. From NIH?

Senator LANDRIEU. From NIH. Thank you.

Secretary THOMPSON. I would be more than happy to. And if you do not get it within 10 days, call me. Will you please?

[The information follows:]

NIH GRANTS AND CONTRACTS AWARDED FOR THE STATE OF LOUISIANA

A list of all NIH grants and contracts awarded to recipients in the State of Louisiana for the past 3 years is being provided under separate cover. In summary, NIH made 334 grant and contract awards for $78.6 million to recipients in Louisiana in fiscal year 2000; 324 awards for $85.8 million in fiscal year 2001; and 344 awards for $117.5 million in fiscal year 2002—a dollar increase of more than 49 percent over fiscal year 2000.

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
FISCAL YEAR 2000				
D43TW001086–02	MATHER, FRANCES J	TULANE UNIVERSITY OF LOUISIANA	INTERNATIONAL TRAINING IN MEDICAL INFORMATICS	$146,438
D43TW001142–02	BEIER, JOHN C	TULANE UNIVERSITY OF LOUISIANA	ACTIONS FOR BUILDING CAPACITY	100,000
D43TW001142–02S1	BEIER, JOHN C	TULANE UNIVERSITY OF LOUISIANA	IMPACT OF MID-GUT BACTERIA ON ANOPHELES MOSQUITOES	40,000
F30DA005743–05	MARTIN-SCHILD, SHERYL B	TULANE UNIVERSITY OF LOUISIANA	TYR–W–MIF–1 AND OPIATE TOLERANCE	53,903
F31DA005907–02	HORNER, KRISTEN A	TULANE UNIVERSITY OF LOUISIANA	CHANGES IN ENDOMORPHINS DURING OPIATE TOLERANCE	19,145
F31DA005926–02	BRADLEY, AMY L	LOUISIANA STATE UNIV-UNIV OF NEW ORLEANS	SYNTHESIS AND DEVELOPMENT OF NEW COCAINE MEDICATIONS	21,189
F31DA005948–02	CZAPLA, MARC A	TULANE UNIVERSITY OF LOUISIANA	ENDOMORPHIN AND CARDIORESPIRATORY CONTROL	20,452
F31DA005968–02	SMITH, REBECCA R	TULANE UNIVERSITY OF LOUISIANA	ENDOMORPHIN PLASTICITY IN CHRONIC PAIN MODELS	34,115
F31DA006010–01	BEYER, CHAD E	LOUISIANA STATE UNIV HSC SHREVEPORT	MEDIAL PREFRONTAL CORTEX'S ROLE IN COCAINE SENSITIZATION	18,654
F31DA006040–01	GREENWELL, THOMAS N	TULANE UNIVERSITY OF LOUISIANA	ENDOMORPHIN-NEUROIMMUNE INTERACTIONS	19,935
F31GM019387–03	HAMILTON, KIMBERLY Y	LOUISIANA STATE UNIV A&M COL BATON ROUGE	CHIRAL SELECTOR IN CAPILLARY ELECTROPHORESIS	21,210
F31GM019876–02	BURSE, JEANINE R	TULANE UNIVERSITY OF LOUISIANA	PAST AND PRESENT BIOINDICATION OF RIVER POLLUTION	23,805
F31GM020437–02	CEDILLO, BERTHA M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	DEVELOPMENT OF A CHIRAL SELECTOR SYSTEM	25,470
F31GM020603–01	WILLIAMS, BRIDGET D	TULANE UNIVERSITY OF LOUISIANA	THE ROLE OF TRACT STABILITY IN TELOMERE MAINTENANCE	33,994
F31GM020686–01	ROBINSON, TERI L	LOUISIANA STATE UNIV A&M COL BATON ROUGE	DENDRIMERS/POLYMERIC SURFACTANTS IN CHIRAL SEPARATIONS	25,573
F31GM020928–01	AUSTIN, JOSEPH	LOUISIANA STATE UNIV HSC SHREVEPORT	MINORITY PRE-DOCTORAL FELLOWSHIP PROGRAM	22,512
F31HG000207–02	SIMMONS-WILLIS, TRACEY A	LOUISIANA STATE UNIV A&M COL BATON ROUGE	MINORITY PRE-DOCTORAL FELLOWSHIP PROGRAM	13,896
F31NS011180–01	CLAYTON BAUCOM, CATHERINE A	TULANE UNIVERSITY OF LOUISIANA	HUMAN HAND PREFERENCE—STRUCTURAL FUNCTIONAL MRI STUDIES	20,830
F32AA005543–02	ZHANG, ZILI	LOUISIANA STATE UNIV HSC NEW ORLEANS	POSTTRANSLATIONAL INHIBITION OF TNF ALPHA BY ALCOHOL	40,936
F32DA005877–03	STAFFORD, DAVID A	LOUISIANA STATE UNIV HSC SHREVEPORT	DRUG EFFECTS ON COCAINE PAIRED CONDITIONED REINFORCERS	40,936
F32DK009931–02	ROSS, DONNA M	LOUISIANA STATE UNIV HSC SHREVEPORT	RENAL CAPILLARY FAILURE IN DIABETIC NEPHROPATHY	32,416
F32EY006996–02	LOUTSCH, JEANNETTE M	LOUISIANA STATE UNIV HSC NEW ORLEANS	OCULAR HSV1 REACTIVATION—CONTROL BY THE LAT DOMAIN	39,232
F32HD008390–03	GULLEDGE, CYNTHIA C	TULANE UNIVERSITY OF LOUISIANA	MECHANISMS OF OPIOID MODULATION OF MATERNAL BEHAVIOR	37,516
G11HD034961–03	ISLAND, GLENDA J	GRAMBLING STATE UNIVERSITY	GSU RESEARCH ADMINISTRATION INFRASTRUCTURE PROGRAM	91,749
G11HD038437–01	OSAGIE, EMMANUEL I	SOUTHERN UNIV A&M COL BATON ROUGE	EXTRAMURAL RESEARCH DEVELOPMENT AWARD	1
G20RR015079–01	BAKER, DAVID G	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	TRANSGENIC FACILITIES FOR NUTRITIONAL RESEARCH	141,322
K01CA078318–02	HEMENWAY, CHARLES S	TULANE UNIVERSITY OF LOUISIANA	BMI1 INTERACTING PROTEINS IN NEOPLASTIC TRANSFORMATION	109,982
K01GM000707–01	CHETTY, KOTHAPA N	GRAMBLING STATE UNIVERSITY	HYPERCHOLESTEROLEMIA AND REPERFUSION INJURY	22,803
K02DA000204–08	LINDBERG, IRIS	LOUISIANA STATE UNIV HSC NEW ORLEANS	OPIOID PEPTIDE PROCESSING ENZYMES	112,160
K02DA000211–07	FRANCE, CHARLES P	LOUISIANA STATE UNIV HSC NEW ORLEANS	BEHAVIORAL PHARMACOLOGY OF OPIOIDS	37,261
K02DK002605–02	KAPUSTA, DANIEL R	LOUISIANA STATE UNIV HSC NEW ORLEANS	OPIOIDS AND CENTRAL NEURAL REGULATION OF RENAL FUNCTION	94,955
K02MH000967–07	HAYCOCK, JOHN W	LOUISIANA STATE UNIV HSC NEW ORLEANS	HUMAN TYROSINE HYDROXYLASE AND SCHIZOPHRENIA	106,040
K02MH001231–06A1	O'DONNELL, JAMES M	LOUISIANA STATE UNIV HSC SHREVEPORT	NOVEL MECHANISMS OF ANTIDEPRESSANT ACTIVITY	69,863
K07HL003327–05	ALI, JUZAR	LOUISIANA STATE UNIV HSC NEW ORLEANS	TUBERCULOSIS ACADEMIC AWARD—COMPREHENSIVE EDUC PROGRAM	71,033
K08AI001438–05	CHANG, WUN–LING	LOUISIANA STATE UNIV HSC SHREVEPORT	CD4 + T CELL REGULATION—-EFFECTOR CELLS IN BLASTOMYCOSIS	118,800
K08AI001467–03	MASON, ANDREW L	OCHSNER CLINIC FOUNDATION	RETROVIRAL ETIOLOGY OF PRIMARY BILIARY CIRRHOSIS	118,800
K08AI049790–01	PARADA, NEREIDA A	TULANE UNIVERSITY OF LOUISIANA	REGULATION OF IL–2 RECEPTOR BY THE CD4 LIGAND IL–16	110,700

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
K08EY000414–02	COLITZ, CARMEN M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	TELOMERASE FUNCTION AND REGULATION IN THE LENS	104,674
K08HL003569–05	Ortiz, Luis A.	TULANE UNIVERSITY OF LOUISIANA	APOPTOSIS IN PULMONARY FIBROSIS–-ROLE FOR TNF AND P53	114,080
K08MH001706–03	SCHEERINGA, MICHAEL S	TULANE UNIVERSITY OF LOUISIANA	TRAUMATIZED YOUNG CHILDREN–-RISK FOR MALADAPTATION	150,627
K23DC000135–04	FOUNDAS, ANNE L	TULANE UNIVERSITY OF LOUISIANA	NEUROBIOLOGIC SUBSTRATES OF STUTTERING	80,271
K30HL004521–01	FRIEDMAN, MITCHELL	TULANE UNIVERSITY OF LOUISIANA	CLINICAL RESEARCH CURRICULUM AWARD	200,000
M01RR005096–11	CORRIGAN, JAMES J	TULANE UNIVERSITY OF LOUISIANA	GENERAL CLINICAL RESEARCH CENTER	2,223,025
N01AI075327–005	Didier, Elizabeth Schmidt	TULANE UNIVERSITY OF LOUISIANA	PRECLINICAL EVAL. OF THERAPIES FOR MICROSPORIDIAL INFECT	397,907
N01HG065404–000	ROTHSCHILD, HENRY	LOUISIANA STATE UNIV HSC NEW ORLEANS	DETERM. OF GEN. SUSCEPTIBILITY LUNG CANCER FAM. S.O.LA.	184,570
N01HG065404–006	ROTHSCHILD, HENRY	LOUISIANA STATE UNIV HSC NEW ORLEANS	DETERM OF GEN SUSCEPTIBILITY LUNG CANCER	237,874
N01HG065404–007	ROTHSCHILD, HENRY	LOUISIANA STATE UNIV HSC NEW ORLEANS	DETERM OF GEN SUSCEPTIBILITY LUNG CANCER	237,675
P01CA028842–17	CORREA, PELAYO	LOUISIANA STATE UNIV HSC NEW ORLEANS	ETIOLOGIC STUDIES OF GASTRIC CARCINOMA	683,011
P01DK043785–10	GRANGER, D NEIL	LOUISIANA STATE UNIV HSC SHREVEPORT	PATHOPHYSIOLOGY OF INTESTINAL ISCHEMIA/REPERFUSION	1,243,529
P30EY002377–22	KAUFMAN, HERBERT E	LOUISIANA STATE UNIV HSC NEW ORLEANS	CORE GRANT FOR VISION RESEARCH	432,575
P50AA009803–07	SPITZER, JOHN J	LOUISIANA STATE UNIV HSC NEW ORLEANS	ALCOHOL, HIV INFECTION AND HOST DEFENSE	1,707,894
P50AA009803–07S1	SPITZER, JOHN J	LOUISIANA STATE UNIV HSC NEW ORLEANS	ALCOHOL, HIV INFECTION AND HOST DEFENSE	105,817
P51RR000164–39	LAROSA, JOHN C	TULANE UNIVERSITY OF LOUISIANA	REGIONAL PRIMATE RESEARCH CENTER	5,731,111
R01AA008846–08	Bautista, Abraham P.	LOUISIANA STATE UNIV HSC NEW ORLEANS	LIVER AND THE IMMUNODEFICIENCY OF ALCOHOLICS	169,292
R01AA009505–05	PRUETT, STEPHEN B	LOUISIANA STATE UNIV HSC SHREVEPORT	MECHANISMS OF IMMUNOSUPPRESSION BY ONE DOSE OF ETHANOL	154,003
R01AA009876–06	WOLCOTT, ROBERT M	LOUISIANA STATE UNIV HSC SHREVEPORT	FETAL ALCOHOL EFFECTS AND IMMUNE DEVELOPMENT	205,594
R01AA011224–04	GILES, THOMAS D	LOUISIANA STATE UNIV HSC NEW ORLEANS	MODERATE ALCOHOL USE—CARDIOVASCULAR RISKS AND BENEFITS	235,882
R01AA011760–04	MASON, CAROL M	LOUISIANA STATE UNIV HSC NEW ORLEANS	ALCOHOL, TB AND AIDS	181,995
R01AG016592–01A1	BERENSON, GERALD S.	TULANE UNIVERSITY OF LOUISIANA	EVOLUTION OF CARDIOVASCULAR RISK WITH NORMAL AGING	715,752
R01AG017887–01	JAZWINSKI, S MICHAL	LOUISIANA STATE UNIV HSC NEW ORLEANS	NUTRITIONAL AND METABOLIC MECHANISMS OF AGING	336,000
R01AG017981–01	MCLAUGHLIN, MARK L	LOUISIANA STATE UNIV A&M COL BATON ROUGE	BETA-SHEET MIMICS FROM CONSTRAINED DIPEPTIDE UNITS	180,930
R01AG017983–01	HAMMER, ROBERT P	LOUISIANA STATE UNIV A&M COL BATON ROUGE	INHIBITION OF FIBRILLOGENESIS WITH B–STRAND MIMICS	316,180
R01AG017983–01S1	HAMMER, ROBERT P	LOUISIANA STATE UNIV A&M COL BATON ROUGE	INHIBITION OF FIBRILLOGENESIS WITH B–STRAND MIMICS	66,802
R01AG018239–01	GEISELMAN, PAULA J	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	OBESITY PREVENTION AFTER SMOKING CESSATION IN MENOPAUSE	183,750
R01AG018648–01	VANLANDINGHAM, MARK J	TULANE UNIVERSITY OF LOUISIANA	SOCIO-DEMOGRAPHIC IMPACT OF AIDS ON OLDER PERSONS	109,678
R01AI019199–16	KLEI, THOMAS R	LOUISIANA STATE UNIV A&M COL BATON ROUGE	LYMPHATIC LESION PATHOGENESIS IN BRUGIA INFECTED JIRDS	222,143
R01AI022001–16	O'CALLAGHAN, DENNIS J	LOUISIANA STATE UNIV HSC SHREVEPORT	NUCLEIC ACIDS OF HERPES VIRUS INFECTED CELLS	330,781
R01AI031567–06	CHERVENAK, ROBERT P	LOUISIANA STATE UNIV HSC SHREVEPORT	DEVELOPMENTAL BIOLOGY OF T CELL PRECURSORS	178,096
R01AI032556–06A1	FIDEL, PAUL L	LOUISIANA STATE UNIV HSC NEW ORLEANS	MUCOSAL CELL MEDIATED IMMUNITY IN VAGINAL CANDIDIASIS	203,750
R01AI034754–07	Garry, Robert F.	TULANE UNIVERSITY OF LOUISIANA	ALTERATIONS OF ION TRANSPORT BY HIV	236,098
R01AI040667–05	VAN DER HEYDE, HENRI C	LOUISIANA STATE UNIV HSC SHREVEPORT	MECHANISMS WHEREBY CD4 T CELLS ACTIVATE AMI AND CMI	194,558
R01AI041693–03	FIDEL, PAUL L	LOUISIANA STATE UNIV HSC NEW ORLEANS	HORMONAL REGULATION OF VIGINAL IMMUNITY TO C ALBICANS	200,347
R01AI042146–02	MUGGERIDGE, MARTIN I	LOUISIANA STATE UNIV HSC SHREVEPORT	ROLES OF HSV2 MEMBRANE PROTEINS IN MEMBRANE FUSION	173,012
R01AI042350–03	LANDRY, SAMUEL J	TULANE UNIVERSITY OF LOUISIANA	HELPER T CELL EPITOPE IMMUNODOMINANCE	199,020
R01AI042400–01A2	DAVISON, BILLIE B	TULANE UNIVERSITY OF LOUISIANA	A RHESUS MONKEY MODEL OF MALARIA IN PREGNANCY	566,402

R01AI042777–03	CLEMENTS, JOHN D	TULANE UNIVERSITY OF LOUISIANA	MECHANISM OF CHOLERA TOXIN AND E COLI LT ADJUVANTICITY	195,482
R01AI043000–02	KOUSOULAS, KONSTANTIN GUS	LOUISIANA STATE UNIV A&M COL BATON ROUGE	GENETICS & FUNCTIONS OF HSV1 GK IN VIRUS ENTRY & EGRESS	279,406
R01AI044424–03	STACZEK, JOHN	LOUISIANA STATE UNIV HSC SHREVEPORT	CHIMERIC VIRUS VACCINES FOR P AERUGINOSA INFECTION	183,600
R01AI045151–01A1	FREYTAG, LUCIA C	TULANE UNIVERSITY OF LOUISIANA	MUCOSAL IMMUNIZATION—PREVENTION OF SYSTEMIC CANDIDIASIS	222,750
R01AI045725–01A1	GILLIS, THOMAS P	NATIONAL HANSEN'S DISEASE PROGRAM	DEVELOP AND EVALUATE NEW LEPROSY AND TB VACCINES	110,275
R01AI046275–02	Robinson, JAMES E	TULANE UNIVERSITY OF LOUISIANA	RHESUS MABS FROM SHIV INFECTED MACAQUES	220,613
R01AI048499–01	ROOP, ROY M	LOUISIANA STATE UNIV HSC SHREVEPORT	BRUCELLA STATIONARY PHASE GENE EXPRESSION AND VIRULENCE	315,000
R01AR045982–03	ALA–KOKKA, LEENA M	TULANE UNIVERSITY OF LOUISIANA	MUTATIONS CAUSING DISC DISEASE AND SCIATICA	280,549
R01AR046976–02	KIMPEL, DONALD L	LOUISIANA STATE UNIV HSC SHREVEPORT	NOVEL IMAGING TECHNOLOGIES FOR RHEUMATOID ARTHRITIS	286,000
R01CA054152–09	HILL, STEVEN M	TULANE UNIVERSITY OF LOUISIANA	NEUROENDOCRINE INFLUENCES ON MAMMARY CANCER	178,276
R01CA054576–07	Dash, Srikanta A.	TULANE UNIVERSITY OF LOUISIANA	HEPATITIS C VIRUS AND HEPATOCELLULAR CARCINOMA A	244,525
R01CA065600–04	SPARKS, RODNEY L	TULANE UNIVERSITY OF LOUISIANA	CARCINOGENESIS AND LOSS OF DIFFERENTIATION CONTROL	173,347
R01CA075190–03	BERKEL, HANS J	LOUISIANA STATE UNIV HSC SHREVEPORT	CHEMOPREVENTION OF ADENOMATOUS COLORECTAL POLYPS	651,800
R01CA075613–02	HWANG, DANIEL H	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	CYCLOOXYGENASE AND TUMORIGENESIS	189,257
R01CA078335–02	GNARRA, JAMES R	LOUISIANA STATE UNIV HSC NEW ORLEANS	HGF/SF SIGNALING BY THE VHL TUMOR SUPPRESSOR	216,802
R01CA078335–02S1	GNARRA, JAMES R	LOUISIANA STATE UNIV HSC NEW ORLEANS	HGF/SF SIGNALING BY THE VHL TUMOR SUPPRESSOR	70,117
R01CA080149–02	MATHIS, J MICHAEL	LOUISIANA STATE UNIV HSC SHREVEPORT	ADENOVIRUS BASED P53 GENE THERAPY FOR OVARIAN CANCER	107,690
R01CA081125–02	SCHWARZENBERGER, PAUL O	LOUISIANA STATE UNIV HSC NEW ORLEANS	IL–17 AND HEMATOPOIESIS	137,290
R01CA081506–01A1	EHRLICH, MELANIE	TULANE UNIVERSITY OF LOUISIANA	DNA HYPOMETHYLATION AND CANCER	219,564
R01CA082689–02	OCHOA, AUGUSTO C.	LOUISIANA STATE UNIV HSC NEW ORLEANS	INDUCTION OF ANERGY AND ALTERED SIGNAL TRANSDUCTION	201,812
R01CA083823–01	Levy, Laura S.	TULANE UNIVERSITY OF LOUISIANA	SELECTIVE FORCES OPERATIVE IN FELV INFECTION	237,309
R01CA085693–01	HARRISON, LYNN	LOUISIANA STATE UNIV HSC SHREVEPORT	DNA REPAIR OF MULTIPLY DAMAGED SITES IN CELLS	218,250
R01DA005084–13	LINDBERG, IRIS	LOUISIANA STATE UNIV HSC NEW ORLEANS	OPIOID PEPTIDE SYNTHESIZING ENZYMES	175,109
R01DA006013–08	GOEDERS, NICHOLAS E	LOUISIANA STATE UNIV HSC SHREVEPORT	ENVIRONMENTAL INFLUENCES ON COCAINE SELF ADMINISTRATION	207,513
R01DA008255–06	VARNER, KURT J.	LOUISIANA STATE UNIV HSC NEW ORLEANS	CHRONIC COCAINE/STIMULANTS—CARDIOVASCULAR CONSEQUENCES	170,943
R01DA009157–05	FRANCE, CHARLES P	LOUISIANA STATE UNIV HSC NEW ORLEANS	DISCRIMINATIVE EFFECTS OF BENZODIAZEPINE WITHDRAWAL	31,209
R01DA009820–05	GLOWA, JOHN R	LOUISIANA STATE UNIV HSC SHREVEPORT	DETERMINANTS OF DRUG EFFECTS ON DRUG MAINTAINED BEHAVIOR	318,520
R01DA009820–05S1	GLOWA, JOHN R	LOUISIANA STATE UNIV HSC SHREVEPORT	DETERMINANTS OF DRUG EFFECTS ON DRUG MAINTAINED BEHAVIOR	58,144
R01DA011417–02	Moerschbaecher, Joseph M.	LOUISIANA STATE UNIV HSC NEW ORLEANS	CANNABINOID ABUSE EFFECTS ON LEARNING AND MEMORY	189,130
R01DA011528–04	TRUDELL, MARK L	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	SYNTHESIS OF POTENTIAL COCAINE ABUSE THERAPEUTICS	251,372
R01DA011655–03	ZADINA, JAMES E	TULANE UNIVERSITY OF LOUISIANA	NEUROBIOLOGY OF ENDOMORPHINS	134,463
R01DA011939–01A2	Harlan, Richard E	TULANE UNIVERSITY OF LOUISIANA	THALAMOSTRIATAL MECHANISMS OF MORPHINE ACTION	187,166
R01DA012267–02	HARRISON, MURELLE G	SOUTHERN UNIV A&M COL BATON ROUGE	PREVENTING SUBSTANCE USE IN RURAL AFRICAN–AMERICAN YOUTH	571,834
R01DA012427–01A1	WINSAUER, PETER J	LOUISIANA STATE UNIV HSC NEW ORLEANS	COCAINE SELF-ADMINSTRATION: EFFECTS ON LEARNING	91,369
R01DA012427–01A1S1	WINSAUER, PETER J	LOUISIANA STATE UNIV HSC NEW ORLEANS	COCAINE SELF-ADMINSTRATION: EFFECTS ON LEARNING	10,010
R01DA012703–02	TRUDELL, MARK L	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	NOVEL NICOTINIC RECEPTOR MEDIATED THERAPEUTIC AGENTS	287,756
R01DC000303–13	GUTH, PAUL S	TULANE UNIVERSITY OF LOUISIANA	PHARMACOLOGY OF VESTIBULAR NEUROTRANSMISSION	212,969
R01DC003679–02	Hood, Linda Jean	LOUISIANA STATE UNIV HSC NEW ORLEANS	AUDITORY GENETIC STUDIES OF HEREDITARY HEARING LOSS	201,335
R01DC003792–02	CAPRIO, JOHN T	LOUISIANA STATE UNIV A&M COL BATON ROUGE	ENCODING OF BIOLOGICALLY RELEVANT ODOR SIGNALS	310,659
R01DC003896–02	Ricci, Anthony J	LOUISIANA STATE UNIV HSC NEW ORLEANS	ENDOGENOUS FACTORS REGULATING TRANSDUCER ADAPTATION	169,287

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
R01DC003896–02S1	Ricci, Anthony J	LOUISIANA STATE UNIV HSC NEW ORLEANS	ENDOGENOUS FACTORS REGULATING TRANSDUCER ADAPTATION	19,770
R01DC004196–02	Keats, Bronya J.	LOUISIANA STATE UNIV HSC NEW ORLEANS	ID OF THE MOUSE DEAFNESS (DN) GENE ON CHROMOSOME 19	217,521
R01DE008851–10	BLOCK, MICHAEL S	LOUISIANA STATE UNIV HSC NEW ORLEANS	PROSPECTIVE EVALUATION OF IMPLANT SUPPORTED BRIDGES	109,415
R01DE008911–09	WISE, GARY E	LOUISIANA STATE UNIV A&M COL BATON ROUGE	MOLECULAR BASIS OF TOOTH ERUPTION	168,830
R01DE012178–03	FIDEL, PAUL L	LOUISIANA STATE UNIV HSC NEW ORLEANS	ORAL IMMUNE DYSFUNCTION AND CANDIDIASIS IN HIV INFECTION	222,477
R01DE012178–03S1	FIDEL, PAUL L	LOUISIANA STATE UNIV HSC NEW ORLEANS	ORAL IMMUNE DYSFUNCTION AND CANDIDIASIS IN HIV INFECTION	105,767
R01DE012178–03S2	FIDEL, PAUL L	LOUISIANA STATE UNIV HSC NEW ORLEANS	ORAL IMMUNE DYSFUNCTION AND CANDIDIASIS IN HIV INFECTION	25,622
R01DE012187–05	SIXBEY, JOHN W.	LOUISIANA STATE UNIV HSC SHREVEPORT	DETERMINANTS OF EPSTEIN BARR VIRUS MUCOSAL PATHOGENESIS	219,839
R01DE012329–02	CHEN, YIPING	TULANE UNIVERSITY OF LOUISIANA	MOLECULAR MECHANISMS OF VERTEBRATE TOOTH INITIATION	175,255
R01DE012916–02	AMEDEE, ANGELA M	TULANE UNIVERSITY OF LOUISIANA	SIV MACAQUE MODEL FOR BREAST MILK TRANSMISSION OF HIV	284,210
R01DK034286–16	RABON, EDWIN C	TULANE UNIVERSITY OF LOUISIANA	GASTRIC ACID SECRETION: CATION BINDING IN H,K–ATPASE	188,931
R01DK039232–11	CARDELLI, JAMES A	LOUISIANA STATE UNIV HSC SHREVEPORT	REGULATION OF PHAGOCYTOSIS	179,990
R01DK041868–10	HWANG, DANIEL H	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	DIETARY N 3 FATTY ACIDS AND EXPRESSION OF CYCLOOXYGENASE	185,627
R01DK042714–08S1	HORNBY, PAMELA J	LOUISIANA STATE UNIV HSC NEW ORLEANS	CNS AUTONOMIC PATHWAYS AND GASTROINTESTINAL FUNCTION	10,000
R01DK042714–09	HORNBY, PAMELA J	LOUISIANA STATE UNIV HSC NEW ORLEANS	CNS AUTONOMIC PATHWAYS AND GASTROINTESTINAL FUNCTION	177,080
R01DK043337–08	KAPUSTA, DANIEL R	LOUISIANA STATE UNIV HSC NEW ORLEANS	OPIOIDS AND CENTRAL NEURAL REGULATION OF RENAL FUNCTION	142,501
R01DK044628–06	Inscho, Edward W.	TULANE UNIVERSITY OF LOUISIANA	PURINERGIC REGULATION OF THE RENAL MICROVASCULATURE	231,761
R01DK045278–08	York, David A.	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	ENTEROSTATIN REGULATION OF FAT INTAKE	213,473
R01DK045449–07	BARICOS, WILLIAM H	TULANE UNIVERSITY OF LOUISIANA	PA/PLASMIN/GELATINASE CASCADE IN DIABETIC NEPHROPATHY	208,020
R01DK046935–06	Lancaster, Jack R.	LOUISIANA STATE UNIV HSC NEW ORLEANS	NITROGEN AND OXYGEN RADICAL INTERACTIONS IN SURGERY	193,177
R01DK047211–06	VEDECKIS, WAYNE V.	LOUISIANA STATE UNIV HSC NEW ORLEANS	REGULATION OF GLUCOCORTICOID RECEPTOR GENE EXPRESSION	175,335
R01DK047348–07	BERTHOUD, HANS–RUDOLF	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	AUTONOMIC REGULATION OF FOOD INTAKE AND METABOLISM	174,607
R01DK047663–06	GRISHAM, MATTHEW B	LOUISIANA STATE UNIV HSC SHREVEPORT	ADHESION MOLECULE EXPRESSION IN CHRONIC GUT INFLAMMATION	180,366
R01DK049703–05	LINDBERG, IRIS	LOUISIANA STATE UNIV HSC NEW ORLEANS	CONTROL OF PEPTIDE HORMONE BIOSYNTHESIS BY PC2 AND 7B2	169,680
R01DK049703–05S1	LINDBERG, IRIS	LOUISIANA STATE UNIV HSC NEW ORLEANS	CONTROL OF PEPTIDE HORMONE BIOSYNTHESIS BY PC2 AND 7B2	65,780
R01DK049703–05S2	LINDBERG, IRIS	LOUISIANA STATE UNIV HSC NEW ORLEANS	CONTROL OF PEPTIDE HORMONE BIOSYNTHESIS BY PC2 AND 7B2	28,749
R01DK050736–04	LOVEJOY, JENNIFER C	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	MENOPAUSE EFFECT ON OBESITY, ENERGY BALANCE AND INSULIN	221,244
R01DK051392–04	HAMMOND, TIMOTHY G	TULANE UNIVERSITY OF LOUISIANA	MECHANISMS OF URINARY BLADDER ENDOSOMAL FUSION	226,264
R01DK052968–02	Stephens, Jacqueline M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	REGULATION AND ACTIVATION OF STATS IN ADIPOCYTES	176,467
R01DK053113–02	SMITH, BRENDA K	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	TASTE AND GENETIC MECHANISMS OF MACRONUTRIENT SELECTION	210,114
R01DK053697–04	CORREA, PELAYO	LOUISIANA STATE UNIV HSC NEW ORLEANS	HELICOBACTER INFECTION AND GROWTH OF CHILDREN	116,698
R01DK053903–02	Harris, Ruth B.	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	LEPTIN AND PERIPHERAL GLUCOSE METABOLISM	178,683
R01DK054880–02	KASTIN, ABBA J	TULANE UNIVERSITY OF LOUISIANA	BLOOD/BRAIN BARRIER AND LEPTIN TRANSPORT IN OBESITY	318,730
R01DK054952–01A2	HAMM, L. LEE	TULANE UNIVERSITY OF LOUISIANA	REGULATION OF CITRATE TRANSPORT	198,450
R01DK055626–01A2	AWAYDA, MOUHAMED S.	TULANE UNIVERSITY OF LOUISIANA	KINASE REGULATION OF THE EPITHELIAL NA CHANNEL	210,625
R01DK056264–01A1	El-Dahr, Samir S.	TULANE UNIVERSITY OF LOUISIANA	INDUCIBLE DYSPLASTIC NEPHROPATHY IN B2-DEFICENT MICE	267,300
R01DK057242–01	BERTHOUD, HANS–RUDOLF	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	FUNCTIONAL ORGANIZATION OF THE VAGAL–ENTERIC INTERFACE	191,743
R01DK057446–02	LOVEJOY, JENNIFER C	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	INTERNET-AIDED PREVENTION OF PREGNANCY-INDUCED OBESITY	226,282

R01DK057476–02	MARTIN, PAMELA D	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	PRIMARY CARE OFFICE MANAGEMENT OF OBESITY	190,358
R01DK058152–01	KOZAK, LESLIE P	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	GENETICS OF DEVELOPMENTAL PLASTICITY IN THE ADIPOCYTE	419,610
R01ES004344–10	BACKES, WAYNE L	LOUISIANA STATE UNIV HSC NEW ORLEANS	TOXICOLOGICAL SIGNIFICANCE OF ALKYLBENZENE METABOLISM	197,329
R01ES006766–07	Brody, Arnold R	TULANE UNIVERSITY OF LOUISIANA	GROWTH FACTORS IN ASBESTOS INDUCED PULMONARY FIBROSIS	246,479
R01ES007815–05	Deutsch, Walter A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	OXIDATIVE DNA DAMAGE AND THE ANALYSIS OF 8-OXOG REPAIR	239,906
R01ES008663–04	FRIEDMAN, MITCHELL	TULANE UNIVERSITY OF LOUISIANA	BIOCHEMICAL MECHANISM FOR OZONE PATHOLOGY	190,024
R01ES009158–04	PRUETT, STEPHEN B	LOUISIANA STATE UNIV HSC SHREVEPORT	MECHANISMS OF IMMUNOTOXICITY OF CHEMICAL STRESSORS	113,432
R01ES009870–01A1	MEHENDALE, HARIHARA M	UNIVERSITY OF LOUISIANA AT MONROE	DIETARY RESTRICTION AND TOXICANT-INDUCED LIVER DISEASE	224,993
R01ES010046–01A1	LASKY, JOSEPH A	TULANE UNIVERSITY OF LOUISIANA	DISRUPTION OF PDGF SIGNAL TRANSDUCTION IN LUNG FIBROSIS	222,750
R01EY002672–22	KAUFMAN, HERBERT E	LOUISIANA STATE UNIV HSC NEW ORLEANS	OCULAR HERPES SIMPLEX	446,207
R01EY003311–21	KLYCE, STEPHEN D	LOUISIANA STATE UNIV HSC NEW ORLEANS	INTEGRATED ASSESSMENT OF CORNEAL FORM AND FUNCTION	254,318
R01EY004928–18	BAZAN, HAYDEE E	LOUISIANA STATE UNIV HSC NEW ORLEANS	CORNEAL LIPID METABOLISM AND RESPONSE TO INFLAMMATION	191,428
R01EY006311–14	HILL, JAMES M	LOUISIANA STATE UNIV HSC NEW ORLEANS	OCULAR HSV—LATENCY, REACTIVATION, AND RECURRENCE	225,251
R01EY006635–14	BAZAN, HAYDEE E	LOUISIANA STATE UNIV HSC NEW ORLEANS	CELL SIGNAL TRANSDUCTION IN CORNEAL WOUND HEALING	216,772
R01EY007380–11A2	MENERAY, MICHELE A	LOUISIANA STATE UNIV HSC NEW ORLEANS	INTERACTIVE CELLULAR CONTROLS LACRIMAL GLAND FUNCTION	277,869
R01EY008871–10	HILL, JAMES M	LOUISIANA STATE UNIV HSC NEW ORLEANS	OCULAR PATHOGENESIS AND THERAPY OF BACTERIAL KERATITIS	286,084
R01EY010974–05	O'CALLAGHAN, RICHARD J	LOUISIANA STATE UNIV HSC NEW ORLEANS	STAPH KERATITIS—MECHANISMS/ARRESTING OF CORNEAL DAMAGE	249,898
R01EY011610–03	BURGOYNE, CLAUDE F	LOUISIANA STATE UNIV HSC NEW ORLEANS	IOP RELATED FORCE AND FAILURE IN THE OPTIC NERVE HEAD	274,018
R01EY012367–02	JACOB, JEAN T	LOUISIANA STATE UNIV HSC NEW ORLEANS	EPITHELIALIZATION OF TISSUE ENGINEERED CORNEAS	186,119
R01EY012416–02	BEUERMAN, ROGER W	LOUISIANA STATE UNIV HSC NEW ORLEANS	REGULATION OF PROTEIN SYNTHESIS IN THE LACRIMAL GLAND	220,278
R01EY012540–02	PALKAMA, ARTO K	LOUISIANA STATE UNIV HSC NEW ORLEANS	AQUEOUS OUTFLOW AND STRUCTURAL CORRELATIONS	332,155
R01EY012602–03	ALLIEGRO, MARK C.	LOUISIANA STATE UNIV HSC NEW ORLEANS	CONTROL OF VEGF STIMULATED ENDOTHELIAL PROLIFERATION	170,373
R01EY012701–01A1	CHANDRASEKHER, GUDISEVA	LOUISIANA STATE UNIV HSC NEW ORLEANS	GROWTH FACTOR RECEPTOR MEDITATED SIGNAL MECHANISMS LENS	174,794
R01EY012887–01	KHOOBEHI, BAHRAM	LOUISIANA STATE UNIV HSC NEW ORLEANS	RETINAL AND CHOROIDAL BLOOD FLOW IMAGING	213,024
R01EY012961–01	O'CALLAGHAN, RICHARD J	LOUISIANA STATE UNIV HSC NEW ORLEANS	MECHANISMS AND THERAPY OF BACTERIAL KERATITIS	284,555
R01GM020818–27	RHOADS, ROBERT E.	LOUISIANA STATE UNIV HSC SHREVEPORT	REGULATION OF EUKARYOTIC PROTEIN SYNTHESIS INITITATION	311,655
R01GM039844–09S1	WARNER, ISIAH M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	BIOANALYTICAL SEPARATIONS USING CHIRAL POLYMERS	18,277
R01GM039844–10	WARNER, ISIAH M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	BIOANALYTICAL SEPARATIONS USING CHIRAL POLYMERS	243,454
R01GM045668–08	DEININGER, Prescott L	TULANE UNIVERSITY OF LOUISIANA	HUMAN DIMORPHISMS BY SINE MASTER GENES	234,512
R01GM045842–08	Gross, David S.	LOUISIANA STATE UNIV HSC SHREVEPORT	STRUCTURE/REGULATION OF THE YEAST HSP90 GENES	161,768
R01GM047789–16	TATCHELL, Kelly G.	LOUISIANA STATE UNIV HSC SHREVEPORT	GENETIC ANALYSIS OF PROTEIN PHOSPHATASE I IN YEAST	192,414
R01GM051261–04	WALDROP, GROVER L	LOUISIANA STATE UNIV A&M COL BATON ROUGE	CATALYTIC MECHANISM OF BIOTIN DEPENDENT ENZYMES	92,391
R01GM051521–07	WITT, STEPHEN N.	LOUISIANA STATE UNIV HSC SHREVEPORT	KINETICS AND MECHANISM OF THE HEAT SHOCK 70 PROTEIN DNAK	194,117
R01GM056526–04	LUSTIG, ARTHUR J.	TULANE UNIVERSITY OF LOUISIANA	REGULATION OF TELOMERE DYNAMICS IN YEAST	228,650
R01GM056835–03	MCLAUGHLIN, MARK L	LOUISIANA STATE UNIV A&M COL BATON ROUGE	PEPTIDES ACTIVE AGAINST INTRACELLULAR PATHOGENIC DISEASE	166,651
R01GM058843–02	LIMBACH, PATRICK A.	LOUISIANA STATE UNIV A&M COL BATON ROUGE	IDENTIFICATION OF MODIFIED NUCLEOSIDES IN RIBOSOMAL RNA	126,851
R01HD008431–25	KOZAK, LESLIE P	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	MOLECULAR GENETICS OF THERMOGENESIS	302,854
R01HD035245–04	Muneoka, Ken	TULANE UNIVERSITY OF LOUISIANA	MSX GENES IN WOUND HEALING AND REGENERATION	152,788
R01HD036822–02	WANG, YU–PING	LOUISIANA STATE UNIV HSC SHREVEPORT	PLACENTAL FUNCTION IN PREECLAMPSIA	137,077
R01HD037811–01A1	GASSER, RAYMOND F	LOUISIANA STATE UNIV HSC NEW ORLEANS	HUMAN EMBRYO SECTIONS ON COMPUTER DISKS FOR EDUCATION	367,391

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R01HD039104–01	WILLIAMSON, DONALD A.	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	INTERNET-BASED OBESITY PREVENTION FOR BLACK ADOLESCENTS	157,972
R01HG001499–04	SOPER, Steven A	LOUISIANA STATE UNIV A&M COL BATON ROUGE	HIGH THROUGHPUT DNA SEQUENCING USING NANO–REACTORS	430,128
R01HG001777–03	LIMBACH, PATRICK A.	LOUISIANA STATE UNIV A&M COL BATON ROUGE	DNA SEQUENCING BY MASS SPECTROMETRIC METHODS	136,475
R01HL018426–26S1	Navar, L. Gabriel	TULANE UNIVERSITY OF LOUISIANA	REGULATION OF RENAL HEMODYNAMICS	10,434
R01HL018426–27	Navar, L. Gabriel	TULANE UNIVERSITY OF LOUISIANA	REGULATION OF RENAL HEMODYNAMICS	281,221
R01HL026371–19	Navar, L. Gabriel	TULANE UNIVERSITY OF LOUISIANA	RENAL FUNCTIONAL DERANGEMENTS IN HYPERTENSION	231,372
R01HL026371–19S1	Navar, L. Gabriel	TULANE UNIVERSITY OF LOUISIANA	RENAL FUNCTIONAL DERANGEMENTS IN HYPERTENSION	73,309
R01HL026441–20	GRANGER, D NEIL	LOUISIANA STATE UNIV HSC SHREVEPORT	TRANSCAPILLARY FLUID EXCHANGE	243,130
R01HL045670–08S1	BOUCHARD, CLAUDE	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	HERITAGE-GENETICS, RESPONSE TO EXERCISE, RISK FACTORS	284,054
R01HL045670–09	BOUCHARD, CLAUDE	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	HERITAGE-GENETICS, RESPONSE TO EXERCISE, RISK FACTORS	915,078
R01HL054797–07A1	KORTHUIS, RONALD J	LOUISIANA STATE UNIV HSC SHREVEPORT	PRECONDITIONING: PMN ADHESION AND MICROVASCULAR INJURY	290,000
R01HL056241–03	LEFEVRE, MICHAEL	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	EFFICACY OF DIET THERAPY IN SUBJECTS AT RISK FOR CHD	323,842
R01HL058409–04	AGRAWAL, KRISHNA C	TULANE UNIVERSITY OF LOUISIANA	MECHANISMS OF HEMATOLOGIC ABNORMALITIES IN AIDS	274,486
R01HL058610–04	HOYLE, GARY W	TULANE UNIVERSITY OF LOUISIANA	PULMONARY FIBROSIS IN PDGF TRANSGENIC MICE	263,426
R01HL059699–03	IMIG, JOHN D	TULANE UNIVERSITY OF LOUISIANA	OXYGENASE METABOLITES AND RENAL VASCULAR ACTIVITY	92,972
R01HL059724–04	SHELLITO, JUDD E	LOUISIANA STATE UNIV HSC NEW ORLEANS	T LYMPHOCYTE SUBSETS AND HOST DEFENSE AGAINST P CARINII	335,478
R01HL059879–02	CLAYCOMB, WILLIAM C	LOUISIANA STATE UNIV HSC NEW ORLEANS	NOVEL GENE DISCOVERED IN THE HEART	206,942
R01HL060300–04	HE, JIANG	TULANE UNIVERSITY OF LOUISIANA	EPIDEMIOLOGY STUDIES OF DIETARY FIBER AND BLOOD PRESSURE	129,736
R01HL060532–04	Brody, Arnold R	TULANE UNIVERSITY OF LOUISIANA	EPITHELIAL GROWTH FACTORS IN ENVIRONMENTAL LUNG DISEASE	280,370
R01HL060849–02	LEFER, DAVID J	LOUISIANA STATE UNIV HSC SHREVEPORT	MECHANISMS OF MYOCARDIAL REPERFUSION INJURY—DIABETES	176,994
R01HL061271–02	Kolls, Jay K.	LOUISIANA STATE UNIV HSC NEW ORLEANS	NON CD4 HOST DEFENSE AGAINST P CARINII PNEUMONIA	73,902
R01HL061934–04	MORRIS, CINDY A	LOUISIANA STATE UNIV HSC NEW ORLEANS	MOLECULAR MECHANISM OF TAT INDUCED ANGIOGENESIS	214,500
R01HL062000–01A2	HYMAN, ALBERT L	TULANE UNIVERSITY OF LOUISIANA	CARDIOPULMONARY SURGERY RESEARCH	257,450
R01HL062052–03	Kolls, Jay K.	LOUISIANA STATE UNIV HSC NEW ORLEANS	CD8 AND GAMMA/DELTA T CELLS IN P CARINII PNEUMONIA	250,250
R01HL062147–03	PANDEY, KAILASH N	TULANE UNIVERSITY OF LOUISIANA	ANP RECEPTOR GENE—TARGETING AND EXPRESSION	155,714
R01HL063128–01A2	AGRAWAL, KRISHNA C	TULANE UNIVERSITY OF LOUISIANA	MECHANISMS OF CARDIOVASCULAR COMPLICATIONS IN AIDS	283,597
R01HL063195–02	TRAYANOVA, NATALIA A	TULANE UNIVERSITY OF LOUISIANA	CARDIAC TISSUE STRUCTURE IN THE DEFIBRILLATION PROCESS	147,940
R01HL064555–02	CLARKSON, CRAIG W	TULANE UNIVERSITY OF LOUISIANA	MOLECULAR BASIS FOR DRUG INDUCED CARDIOTOXICITY IN AIDS	183,546
R01HL064577–02	JOHNSON, ROBERT A	TULANE UNIVERSITY OF LOUISIANA	HEMODYNAMIC ROLES OF ENDOGENEOUS CARBON MONOXIDE	166,277
R01MH051175–06	O'DONNELL, JAMES M	LOUISIANA STATE UNIV HSC SHREVEPORT	NEUROPSYCHOPHARMACOLOGY OF CYCLIC AMP PDE INHIBITORS	197,207
R01NS009626–30	LI, YU–TEH	TULANE UNIVERSITY OF LOUISIANA	GLYCOSIDASES AS RELATED TO SPHINGOLIPIDOSES	334,553
R01NS023002–15	BAZAN, NICOLAS G	LOUISIANA STATE UNIV HSC NEW ORLEANS	PHOSPHOLIPIDS AND ARACHIDONIC ACID AND EP	265,361
R01NS025134–11	HAYCOCK, JOHN W	LOUISIANA STATE UNIV HSC NEW ORLEANS	CELLULAR REGULATION OF TYROSINE HYDROXYLASE	207,349
R01NS025987–12S1	PHELPS, CAROL J.	TULANE UNIVERSITY OF LOUISIANA	HYPOPHYSIOTROPIC NEURON DIFFERENTIATION—TARGET FEEDBACK	50,000
R01NS025987–13	PHELPS, CAROL J.	TULANE UNIVERSITY OF LOUISIANA	HYPOPHYSIOTROPIC NEURON DIFFERENTIATION—TARGET FEEDBACK	207,159
R01NS034926–04	TASKER, JEFFREY G	TULANE UNIVERSITY OF LOUISIANA	GLUTAMATE MODULATION OF HYPOTHALAMIC NEURONS	177,854
R01NS036936–03	ERICKSON, JEFFREY D	LOUISIANA STATE UNIV HSC NEW ORLEANS	VESICULAR TRANSPORTER SPECIFICITY	201,699
R01NS036936–03S1	ERICKSON, JEFFREY D	LOUISIANA STATE UNIV HSC NEW ORLEANS	VESICULAR TRANSPORTER SPECIFICITY	50,000

R01NS037070–03	ERZURUMLU, REHA S	LOUISIANA STATE UNIV HSC NEW ORLEANS	CELLULAR MECHANISMS UNDERLYING PATTERN FORMATION	127,909
R01NS037963–03	CANAVIER, CARMEN C	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	FIRING PATTERN REGULATION IN MIDBRAIN DOPAMINE NEURONS	147,768
R01NS039050–01A1	ERZURUMLU, REHA S	LOUISIANA STATE UNIV HSC NEW ORLEANS	SOMATOSENSORY CORTICAL DEVELOPMENT AND PLASTICITY	167,305
R01NS039099–01A1	TASKER, JEFFREY G	TULANE UNIVERSITY OF LOUISIANA	HYPOTHALAMIC SYNCHRONIZATION BY LOCAL GLUTAMATE CIRCUITS	311,088
R01NS039458–01	MAGEE, JEFFERY C	LOUISIANA STATE UNIV HSC NEW ORLEANS	DENDRITIC INTEGRATION IN HIPPOCAMPAL PYRAMIDAL NEURONS	207,276
R03AG018034–01	CHERRY, KATIE E	LOUISIANA STATE UNIV A&M COL BATON ROUGE	PERCEPTIONS OF FORGETFULNESS IN ADULTHOOD	69,247
R03AG018187–01	Inscho, Edward W.	TULANE UNIVERSITY OF LOUISIANA	RENAL MICROVASCULAR FUNCTION IN AGED RATS	74,250
R03AG018600–01	REDDIX, RHODA A	LOUISIANA STATE UNIV HSC NEW ORLEANS	GLIAL CELL DERIVED NEUROTROPHIC FACTOR AND THE AGING GUT	71,500
R03AI042077–03	Malone, John B	LOUISIANA STATE UNIV A&M COL BATON ROUGE	GEOGRAPHIC INFORMATION SYSTEMS & SCHISTOSOMIASIS	72,787
R03CA081602–02	HAGENSEE, MICHAEL E	LOUISIANA STATE UNIV HSC NEW ORLEANS	NONINVASIVE DETECTION OF ANTIBODIES AGAINST HPV	65,284
R03CA083050–02	YU, HERBERT H	LOUISIANA STATE UNIV HSC SHREVEPORT	ESTROGEN AND INSULIN LIKE GROWTH FACTORS IN BREAST CANCE	71,195
R03CA083095–02	CORREA, PELAYO	LOUISIANA STATE UNIV HSC NEW ORLEANS	HOST RESPONSE TO HELICOBACTER PYLORI INFECTION	66,985
R03CA083632–02	ESPINOZA–DELGADO, IGOR	LOUISIANA STATE UNIV HSC NEW ORLEANS	TRIAL OF BRYOSTATIN/IL–2 TO ENHANCE ANTIGEN PRESENTATION	71,474
R03CA086378–01	HAGENSEE, MICHAEL E	LOUISIANA STATE UNIV HSC NEW ORLEANS	DEVELOPMENT OF A URINE PCR ASSAY FOR HPV DNA DETECTION	69,350
R03CA088135–01	SU, L. J	LOUISIANA STATE UNIV HSC NEW ORLEANS	DIETARY SURVEY INSTRUMENT DEVELOPMENT FOR AN ETHNIC MINO	71,210
R03DA012547–01A1	ROERIG, SANDRA C	LOUISIANA STATE UNIV HSC SHREVEPORT	SPINAL NITRIC OXIDE IN CHRONIC INFLAMMATORY PAIN	69,978
R03DA013421–01	LAHOSTE, GERALD J	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	GAP JUNCTIONS AND DOPAMINE PLASTICITY	71,000
R03DA013546–01	HUANG, TIEN L	XAVIER UNIVERSITY OF LOUISIANA	NOVEL ANTI-PCP AGENTS WITH NEUROPROTECTIVE PROPERTIES	69,975
R03DC003609–03	OETTING, JANNA B	LOUISIANA STATE UNIV A&M COL BATON ROUGE	SLI WITHIN THE CONTEXT OF DIALECT DIVERSITY	55,926
R03DE012944–02	DEE, KAY C	TULANE UNIVERSITY OF LOUISIANA	ADHESION/GROWTH-PROMOTING PROACTIVE DENTAL BIOMATERIALS	36,473
R03DK054971–03	ABDEL–MAGEED, ASIM B	TULANE UNIVERSITY OF LOUISIANA	METALLOTHIONEIN AND PROSTATE TUMORIGENESIS	73,992
R03MH061944–01	NORTHUP, JOHN A	LOUISIANA STATE UNIV A&M COL BATON ROUGE	STAR PROGRAM: EARLY & PREVENTIVE INTERVENTION OF ADHD	73,500
R13GM061083–01	MOUDGIL, GIRISH C	TULANE UNIVERSITY OF LOUISIANA	ALLERGY, IMMUNOLOGY, AND ANESTHETIC ACTION	3,000
R15AI047297–01	ENNIS, D G	UNIVERSITY OF LOUISIANA AT LAFAYETTE	ANALYSIS OF DNA REPAIR AND SOS REGULATION IN BRUCELLA	117,628
R18AI033449–06	FREY, DANIEL J	LOUISIANA ORGAN PROCUREMENT AGENCY	ENHANCING DONOR REGISTRY TO INCREASE DONATION	282,669
R21AR047796–01	PROCKOP, DARWIN J	TULANE UNIVERSITY OF LOUISIANA	EXPANSION OF STEM CELLS FOR SKELETAL TISSUES	74,250
R21CA078693–02	EHRLICH, MELANIE	TULANE UNIVERSITY OF LOUISIANA	PROGENITOR COLONY RT–PCR ANALYSIS IN CML TREATMENT	148,421
R21CA082618–02	NATHAN, CHERIE–ANN O	LOUISIANA STATE UNIV HSC SHREVEPORT	MOLECULAR ANALYSIS OF SURGICAL MARGINS WITH EIF4E IN CAN	122,714
R21CA083198–01A1	OCHOA, AUGUSTO C.	LOUISIANA STATE UNIV HSC NEW ORLEANS	T CELL SIGNAL TRANSDUCTION TO MONITOR HPV VACCINES	141,426
R21CA084095–01	HYMAN, LINDA E	TULANE UNIVERSITY OF LOUISIANA	ELONGIN C: FUNCTION AND ROLE IN VHL DISEASE	148,500
R21CA091785–01	MATHIS, J MICHAEL	LOUISIANA STATE UNIV HSC SHREVEPORT	ROLE OF CYSTATIN M IN BREAST TUMOR PROGRESSION	99,863
R24CA084625–01	SOPER, Steven A	LOUISIANA STATE UNIV A&M COL BATON ROUGE	MICRO-INSTRUMENT PLATFORMS FOR GENETIC-BASED ANALYSES	591,505
R24DA007970–08	KOMISKEY, HAROLD L	XAVIER UNIVERSITY OF LOUISIANA	MIDARP AT XAVIER UNIVERSITY OF LOUISIANA	393,470
R24HL060808–03	STRONG, JACK P	LOUISIANA STATE UNIV HSC NEW ORLEANS	PDAY CARDIOVASCULAR SPECIMEN AND DATA LIBRARY	124,343
R24RR012545–02	BASKIN, GARY B	TULANE UNIVERSITY OF LOUISIANA	ANIMAL MODEL FOR GENE THERAPY OF INHERITED DISORDERS	503,804
R25CA047877–13	LOPEZ–S, ALFREDO	LOUISIANA STATE UNIV HSC NEW ORLEANS	SHORT RESEARCH EXPERIENCES IN CANCER	63,123
R25GM051773–03A1	HIMAYA, M A	GRAMBLING STATE UNIVERSITY	PARTNERSHIP FOR MINORITY ACCESS TO BACCALAUREATE DEGREES	468,130
R25MH058560–03	SAXENA, KRISHAN M	GRAMBLING STATE UNIVERSITY	NIMH HONORS MINORITY HIGH SCHOOL PROGRAM AT GSU	26,001
R29AI039023–05	HOYLE, GARY W	TULANE UNIVERSITY OF LOUISIANA	NEUROGENIC INFLAMMATION IN ASTHMA AND OZONE LUNG INJURY	110,151
R29CA069148–05	DE BENEDETTI, ARRIGO	LOUISIANA STATE UNIV HSC SHREVEPORT	PROTO-ONCOGENE EIF–4E IN BREAST CANCER	101,454

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
R29CA076186–03	MEYERS, SHARI L	LOUISIANA STATE UNIV HSC SHREVEPORT	MOLECULAR MECHANISM OF TRANSFORMATION BY AML1/ETO	100,955
R29DC003280–02S1	Garcia, Meredith M.	TULANE UNIVERSITY OF LOUISIANA	PROTEIN KINASE C IN CENTRAL AUDITORY PLASTICITY	20,000
R29DC003280–03	Garcia, Meredith M.	TULANE UNIVERSITY OF LOUISIANA	PROTEIN KINASE C IN CENTRAL AUDITORY PLASTICITY	98,502
R29DK052148–04	KALOGERIS, THEODORE J	LOUISIANA STATE UNIV HSC SHREVEPORT	NEUROHORMONAL CONTROL OF INTESTINAL APOLIPOPROTEIN A IV	100,588
R29ES007856–05	MORRIS, GILBERT F	TULANE UNIVERSITY OF LOUISIANA	P53 IN ASBESTOS INDUCED LUNG DISEASE	113,433
R29ES009055–03	MILLER, CHARLES A	TULANE UNIVERSITY OF LOUISIANA	ARYL HYDROCARBON RECEPTOR STRUCTURE AND INTERACTIONS	87,585
R29EY012204–03	GLEASON, EVANNA L	LOUISIANA STATE UNIV A&M COL BATON ROUGE	METABOTROPIC GLUTAMATE RECEPTORS ON AMACRINE CELLS	96,588
R29HD036310–05	VEAZEY, RONALD S	TULANE UNIVERSITY OF LOUISIANA	ONTOGENY OF THE NEONATAL MACAQUE IMMUNE SYSTEM	115,261
R29HD036421–04	KUBISCH, HANS M	TULANE UNIVERSITY OF LOUISIANA	MARKER ASSISTED SELECTION OF BOVINE BLASTOCYSTS	57,093
R29HL051306–05	MAJID, DEWAN S	TULANE UNIVERSITY OF LOUISIANA	NITRIC OXIDE AND MEDIATING PRESSURE NATRIURESIS	116,625
R29HL058806–04	CRUMB, WILLIAM J	TULANE UNIVERSITY OF LOUISIANA	CHARACTERIZATION ION CURRENT IN PEDIATRIC HUMAN ATRIA A	84,322
R29MH055654–04	FRICK, PAUL J	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	CALLOUS/UNEMOTIONAL TRAITS AND CONDUCT PROBLEMS	95,780
R29NS033671–05	ELMSLIE, KEITH S	TULANE UNIVERSITY OF LOUISIANA	CALCIUM CHANNELS IN SYMPATHETIC NEURONS	106,366
R29NS035865–04	MAGEE, JEFFERY C	LOUISIANA STATE UNIV HSC NEW ORLEANS	DENDRITIC K+ AND IH CHANNELS IN HIPPOCAMPAL NEURONS	104,280
R37AG006168–15	JAZWINSKI, S MICHAL	LOUISIANA STATE UNIV HSC NEW ORLEANS	CELLULAR AGING IN A YEAST MODEL SYSTEM	411,022
R37AG006168–15S1	JAZWINSKI, S MICHAL	LOUISIANA STATE UNIV HSC NEW ORLEANS	CELLULAR AGING IN A YEAST MODEL SYSTEM	5,000
R37AG006168–15S2	JAZWINSKI, S MICHAL	LOUISIANA STATE UNIV HSC NEW ORLEANS	CELLULAR AGING IN A YEAST MODEL SYSTEM	120,640
R37DK032089–19	BRAY, GEORGE A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	DIETARY OBESITY	293,153
R37DK036013–14	ORLANDO, ROY C	TULANE UNIVERSITY OF LOUISIANA	ESOPHAGEAL CYTOPROTECTION—AGENTS AND MECHANISMS	202,749
R37EY002580–20S2	KAUFMAN, HERBERT E	LOUISIANA STATE UNIV HSC NEW ORLEANS	CORNEAL PRESERVATION AND KERATOPLASTY	165,943
R37MH051853–07	MCCANN, SAMUEL M	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	MECHANISM OF ACTION OF CYTOKINES ON BRAIN AND PITUITARY	290,105
R42CA083756–03	Pincus, Seth H.	NORION DIAGNOSTIC INNOVATIONS, INC.	HIV INFECTIVITY TEST FOR ANTIVIRAL SUSCEPTIBILITY	245,461
R43AI042464–01A2	LO, WAI–CHUN J	ANOMERIC, INC.	RAPID SCREENING OF MICROBES IN URINE	100,000
R43DC004378–01	JUNEAU, ROGER P	SOFTEAR TECHNOLOGIES, LLC	BENEFITS OF A SOFT–SOLID HEARING INSTRUMENT	99,237
R43GM061508–01	SINHA, SUDHIR K	RELIAGENE TECHNOLOGIES, INC.	DIMORPHIC ALU REPEATS–APPLICATION IN IDENTITY TESTING	100,000
R43NS038358–01A2	NARDUCY, KENNETH W	ST CHARLES PHARMACEUTICALS	DEVELOPMENT OF ANALGESICS WITH FEWER SIDE EFFECTS	99,999
R44CA083552–02	MORGAN, LEE R	DEKK–TEC, INC.	ISOPHOSPHORAMIDE MUSTARD—A PHASE 1 STUDY	225,894
R44CA085021–01	MORGAN, LEE R	DEKK–TEC, INC.	DERIVATIVES OF DEMETHYLPENCLOMEDINE: ANTICANCER AGENTS	126,956
S06GM004531–11	IFEANYI, FELIX I	GRAMBLING STATE UNIVERSITY	MBRS SCORE PROGRAM AT GRAMBLING STATE UNIVERSITY	83,072
S06GM004531–11S1	IFEANYI, FELIX I	GRAMBLING STATE UNIVERSITY	MBRS SCORE PROGRAM AT GRAMBLING STATE UNIVERSITY	112,668
S06GM008008–29	STEVENS, CHERYL L	XAVIER UNIVERSITY OF LOUISIANA	MBRS SCORE PROGRAM AT XAVIER UNIVERSITY	587,409
S11ES009996–02	BLAKE, ROBERT C	XAVIER UNIVERSITY OF LOUISIANA	ALTERATION OF GENE REGULATION BY ENVIRONMENTAL COMPOUNDS	1,103,872
S11ES010018–02	MUGANDA, PERPETUA M	SOUTHERN UNIV A&M COL BATON ROUGE	CELLULAR & MOLECULAR TOXICOLOGY OF BUTADIENE	880,496
T32AA007577–02	BAGBY, GREGORY J	LOUISIANA STATE UNIV HSC NEW ORLEANS	BIOMEDICAL ALCOHOL RESEARCH TRAINING PROGRAM	186,499
T32CA065436–04	JAFFE, BERNARD M	TULANE UNIVERSITY OF LOUISIANA	RESEARCH TRAINING IN SURGICAL ONCOLOGY (T32)	35,288
T32DA007311–02	GOEDERS, NICHOLAS E	LOUISIANA STATE UNIV HSC SHREVEPORT	STRESS AND THE NEUROBIOLOGY OF DRUG AND ALCOHOL DEPENDE	260,724
T34GM007716–22	BIRDWHISTELL, TERESA	XAVIER UNIVERSITY OF LOUISIANA	MARC UNDERGRADUATE STUDENT TRAINING IN ACADEMIC RESEARCH	512,916
T34GM008714–03	HIMAYA, M A	GRAMBLING STATE UNIVERSITY	U STAR PROGRAM FOR MARC AT GRAMBLING STATE UNIVERSITY	169,093

T34MH017102–18	SAXENA, KRISHAN M	GRAMBLING STATE UNIVERSITY	NIMH COR HONORS UNDERGRADUATE PROGRAM AT GSU	78,921
U01AI032913–09	VAN DYKE, RUSSELL B	TULANE UNIVERSITY OF LOUISIANA	TULANE/LSU PEDIATRIC AIDS CLINICAL TRIALS UNIT	869,072
U01AI038844–04S1	Lertora, Juan J. L.	TULANE UNIVERSITY OF LOUISIANA	AIDS CLINICAL TRIALS UNIT	656,013
U01AI042178–08S2	BESCH, CERYL L	TULANE UNIVERSITY OF LOUISIANA	LOUISIANA COMMUNITY AIDS RESEARCH PROGRAM	201,108
U01AI042178–09	MUSHATT, DAVID M	TULANE UNIVERSITY OF LOUISIANA	LOUISIANA COMMUNITY AIDS RESEARCH PROGRAM (CPCRA)	734,999
U01CA083014–02	ZAKRIS, ELLEN L	TULANE UNIVERSITY OF LOUISIANA	TULANE AIDS–ASSOCIATED MALIGNANCY CONSORTIUM	146,641
U01DK046636–06S1	HENDRICKS, JAMES B	CHILDREN'S HOSPITAL (NEW ORLEANS)	DIABETES PREVENTION TRIAL–IDDM (DPT–1)	32,167
U01DK048377–07	BRAY, GEORGE A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	NIDDM PRIMARY PREVENTION TRIAL (DPT 2)	647,180
U01DK056990–02	BRAY, GEORGE A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	Clinical Center for Look AHEAD: Health in Diabetes	864,842
U01HD031315–07	WILSON, JOHN T	LOUISIANA STATE UNIV HSC SHREVEPORT	PEDIATRIC PHARMACOLOGY RESEARCH UNIT	299,009
U01HD032844–06	ABDALIAN, SUE E	TULANE UNIVERSITY OF LOUISIANA	ADOLESCENT MEDICINE HIV/AIDS RESEARCH NETWORK	178,365
U01HL038844–14	BERENSON, GERALD S.	TULANE UNIVERSITY OF LOUISIANA	EARLY NATURAL HISTORY OF ARTERIOSCLEROSIS	1,153,179
U01HL057190–04	BRAY, GEORGE A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	DIETARY PATTERNS, SODIUM INTAKE AND BLOOD PRESSURE	169,185
U01HL060571–03	HARSHA, DAVID W	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	PREMIER—LIFESTYLE INTERVENE FOR BLOOD PRESSURE CONTRL	594,383
U01HL066855–01	Webber, Larry S.	TULANE UNIVERSITY OF LOUISIANA	TRIAL OF ACTIVITY FOR ADOLESCENT GIRLS (TAAG)	504,822
U10CA035272–17	KARDINAL, CARL G	OCHSNER CLINIC FOUNDATION	OCHSNER COMMUNITY CLINICAL ONCOLOGY PROGRAM	531,345
U10CA058658–08	MILLS, GLENN M	LOUISIANA STATE UNIV HSC SHREVEPORT	SOUTHWEST ONCOLOGY GROUP	244,025
U10CA063845–06S3	VEITH, ROBERT W	LOUISIANA STATE UNIV HSC NEW ORLEANS	LSUMC MINORITY–BASED COMMUNITY CLINICAL ONCOLOGY PROGRAM	160,768
U10CA063845–06S4	VEITH, ROBERT W	LOUISIANA STATE UNIV HSC NEW ORLEANS	LSUMC MINORITY–BASED COMMUNITY CLINICAL ONCOLOGY PROGRAM	94,893
U10CA063845–06S5	VEITH, ROBERT W	LOUISIANA STATE UNIV HSC NEW ORLEANS	LSUMC MINORITY–BASED COMMUNITY CLINICAL ONCOLOGY PROGRAM	77,070
U19AI045511–02	BEIER, JOHN C	TULANE UNIVERSITY OF LOUISIANA	AFRICAN MALARIA VECTORS	592,666
U42RR003583–14S1	ROWELL, THOMAS J	UNIVERSITY OF LOUISIANA AT LAFAYETTE	ESTABLISHMENT OF A CHIMPANZEE BREEDING/RESEARCH PROGRAM	335,000
U42RR009895–05S2	DRUILHET, ROBERT E	UNIVERSITY OF LOUISIANA AT LAFAYETTE	DEVELOPMENT OF A SPF PIGTAIL MACAQUE BREEDING COLONY	412,500
U42RR015087–01	ROWELL, THOMAS J	UNIVERSITY OF LOUISIANA AT LAFAYETTE	ESTABLISHMENT/MAINTENANCE OF BIOMEDICAL RESEARCH COLONY	820,281
U45ES010664–01	WRIGHT, BEVERLY H	XAVIER UNIVERSITY OF LOUISIANA	WORKER HEALTH AND SAFETY TRAINING COOPERATIVE AGREEMENT	955,608
TOTAL FY 2000				78,633,407
FISCAL YEAR 2001				
D43TW001086–03	MATHER, FRANCES J	TULANE UNIVERSITY OF LOUISIANA	INTERNATIONAL TRAINING IN MEDICAL INFORMATICS	149,371
D43TW001142–03	BEIER, JOHN C	TULANE UNIVERSITY OF LOUISIANA	ACTIONS FOR BUILDING CAPACITY	100,000
F06TW005588–01	BEIER, JOHN C	TULANE UNIVERSITY OF LOUISIANA	Vector ecology of urban malaria in Africa	29,700
F31DA005907–03	HORNER, KRISTEN A	TULANE UNIVERSITY OF LOUISIANA	CHANGES IN ENDOMORPHINS DURING OPIATE TOLERANCE	20,585
F31DA005926–03	BRADLEY, AMY L	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	SYNTHESIS AND DEVELOPMENT OF NEW COCAINE MEDICATIONS	23,099
F31DA005948–03	CZAPLA, MARC A	TULANE UNIVERSITY OF LOUISIANA	ENDOMORPHIN AND CARDIORESPIRATORY CONTROL	21,892
F31DA005968–03	SMITH, REBECCA R	TULANE UNIVERSITY OF LOUISIANA	ENDOMORPHIN PLASTICITY IN CHRONIC PAIN MODELS	35,818
F31DA006040–02	GREENWELL, THOMAS N	TULANE UNIVERSITY OF LOUISIANA	ENDOMORPHIN–NEUROIMMUNE INTERACTIONS	21,431
F31DA014155–01	BANNER, EDITH J	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	Total Synthesis of Novel Decahydroquinolines	22,271
F31DC005116–01	MCINVALE, ANDREW C	TULANE UNIVERSITY OF LOUISIANA	PSD Proteins: Functional Morphology at Auditory Synapses	21,500
F31GM019387–04	HAMILTON, KIMBERLY Y	LOUISIANA STATE UNIV A&M COL BATON ROUGE	CHIRAL SELECTOR IN CAPILLARY ELECTROPHORESIS	22,650

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
F31GM019876–03	BURSE, JEANINE R	TULANE UNIVERSITY OF LOUISIANA	PAST AND PRESENT BIOINDICATION OF RIVER POLLUTION	15,274
F31GM019876–03S1	BURSE, JEANINE R	TULANE UNIVERSITY OF LOUISIANA	PAST AND PRESENT BIOINDICATION OF RIVER POLLUTION	5,575
F31GM020437–03	CEDILLO, BERTHA M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	DEVELOPMENT OF A CHIRAL SELECTOR SYSTEM	24,737
F31GM020686–02	ROBINSON, TERI L	LOUISIANA STATE UNIV A&M COL BATON ROUGE	DENDRIMERS/POLYMERIC SURFACTANTS IN CHIRAL SEPARATIONS	27,013
F31GM020915–01A1	GUTIERREZ, YANIRA I	TULANE UNIVERSITY OF LOUISIANA	PI3K–Mediated Hypoxia Survival Signaling Pathways	24,470
F31HL068296–01	ANDERSON, KIMBERLY M	TULANE UNIVERSITY OF LOUISIANA	Studies of a novel A and B blood group cleaving enzyme	19,000
F31MH012816–01A1	SANTUZZI, ALECIA M	TULANE UNIVERSITY OF LOUISIANA	PREDOCTORAL FELLOWSHIP PROGRAM (DISABILITY)	21,080
F32DA014162–01	DANIEL, JILL M	LOUISIANA STATE UNIV HSC NEW ORLEANS	Effects of Estrogen and Cannabinoids on Learning	33,260
F32DK009931–03	ROSS, DONNA M	LOUISIANA STATE UNIV HSC SHREVEPORT	RENAL CAPILLARY FAILURE IN DIABETIC NEPHROPATHY	40,196
F32DK010151–01	WHITE, CHRISTY L	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	LEPTIN RESPONSIVENESS IN A DIETARY MODEL OF OBESITY	43,772
F32EY013651–01	MARQUART, MARY E	LOUISIANA STATE UNIV HSC NEW ORLEANS	Pseudomonas proteases as ocular virulence factors	41,996
G08LM007108–01A1	PERNOTTO, DENNIS A	LOUISIANA STATE UNIV HSC SHREVEPORT	USING A LOUISIANA NETWORK TO TRAIN/SEARCH NLM DATABASES	49,489
G11HD034961–04	ISLAND, GLENDA J	GRAMBLING STATE UNIVERSITY	GSU RESEARCH INFRASTRUCTURE—PHASE II	81,148
G20RR016930–01	BLANCHARD, JAMES L	TULANE UNIVERSITY OF LOUISIANA	BLDG D RENOV–ANIMAL RESOURCES IMPROVEMENTS	699,950
K01CA078318–03	HEMENWAY, CHARLES S	TULANE UNIVERSITY OF LOUISIANA	BMI1 INTERACTING PROTEINS IN NEOPLASTIC TRANSFORMATION	136,197
K01ES000358–01A1	HUNT, JAY D	LOUISIANA STATE UNIV HSC NEW ORLEANS	Mutation and Environmental Exposures	101,962
K01GM000707–02	CHETTY, KOTHAPA N	GRAMBLING STATE UNIVERSITY	HYPERCHOLESTEROLEMIA AND REPERFUSION INJURY	23,390
K02DA000204–09	LINDBERG, IRIS	LOUISIANA STATE UNIV HSC NEW ORLEANS	OPIOID PEPTIDE PROCESSING ENZYMES	115,525
K02DK002605–03	KAPUSTA, DANIEL R	LOUISIANA STATE UNIV HSC NEW ORLEANS	OPIOIDS AND CENTRAL NEURAL REGULATION OF RENAL FUNCTION	100,440
K02MH000967–08	HAYCOCK, JOHN W	LOUISIANA STATE UNIV HSC NEW ORLEANS	HUMAN TYROSINE HYDROXYLASE AND SCHIZOPHRENIA	109,220
K08AI001438–06	CHANG, WUN–LING	LOUISIANA STATE UNIV HSC SHREVEPORT	CD4 + T CELL REGULATION—EFFECTOR CELLS IN BLASTOMYCOSIS	118,800
K08AI001467–04	MASON, ANDREW L	OCHSNER CLINIC FOUNDATION	RETROVIRAL ETIOLOGY OF PRIMARY BILIARY CIRRHOSIS	118,800
K08AI049790–02	PARADA, NEREIDA A	TULANE UNIVERSITY OF LOUISIANA	REGULATION OF IL–2 RECEPTOR BY THE CD4 LIGAND IL–16	110,700
K08MH001706–04	SCHEERINGA, MICHAEL S	TULANE UNIVERSITY OF LOUISIANA	TRAUMATIZED YOUNG CHILDREN—RISK FOR MALADAPTATION	153,733
K22ES011025–01	DUGAS, TAMMY R	LOUISIANA STATE UNIV HSC SHREVEPORT	COX–2 Mediated Vascular Toxicity of Methylenedianiline	106,080
K22HD001339–01	DONZE, DAVID	LOUISIANA STATE UNIV A&M COL BATON ROUGE	ANALYSIS OF CHROMOSOMAL INSULATOR/BOUNDARY ELEMENTS	133,960
K23DC000135–05	FOUNDAS, ANNE L	TULANE UNIVERSITY OF LOUISIANA	NEUROBIOLOGIC SUBSTRATES OF STUTTERING	74,925
K30HL004521–02	FRIEDMAN, MITCHELL	TULANE UNIVERSITY OF LOUISIANA	CLINICAL RESEARCH CURRICULUM AWARD	200,000
M01RR005096–12	WHELTON, PAUL K	TULANE UNIVERSITY OF LOUISIANA	GENERAL CLINICAL RESEARCH CENTER	2,378,343
P01DK043785–10S1	GRANGER, D NEIL	LOUISIANA STATE UNIV HSC SHREVEPORT	PATHOPHYSIOLOGY OF INTESTINAL ISCHEMIA/REPERFUSION	201,214
P20RR016456–01	WISCHUSEN, EVERETT W	LOUISIANA STATE UNIV A&M COL BATON ROUGE	Louisana Biomedical Research Network	1,928,797
P30EY002377–23	KAUFMAN, HERBERT E	LOUISIANA STATE UNIV HSC NEW ORLEANS	CORE GRANT FOR VISION RESEARCH	490,104
P50AA009803–08	NELSON, STEVE	LOUISIANA STATE UNIV HSC NEW ORLEANS	ALCOHOL, HIV INFECTION AND HOST DEFENSE	1,733,863
P50AA009803–08S1	NELSON, STEVE	LOUISIANA STATE UNIV HSC NEW ORLEANS	ALCOHOL, HIV INFECTION AND HOST DEFENSE	95,126
P51RR000164–40	WHELTON, PAUL K	TULANE UNIVERSITY OF LOUISIANA	REGIONAL PRIMATE RESEARCH CENTER	5,984,645
R01AA009505–06	PRUETT, STEPHEN B	LOUISIANA STATE UNIV HSC SHREVEPORT	MECHANISMS OF IMMUNOSUPPRESSION BY ONE DOSE OF ETHANOL	175,929
R01AA009876–07	WOLCOTT, ROBERT M	LOUISIANA STATE UNIV HSC SHREVEPORT	FETAL ALCOHOL EFFECTS AND IMMUNE DEVELOPMENT	211,762
R01AA010384–06A1	Kolls, Jay K.	LOUISIANA STATE UNIV HSC NEW ORLEANS	ALCOHOL, IMMUNOSUPPRESSION, AND TACE	286,000

R01AA011224–05	GILES, THOMAS D	LOUISIANA STATE UNIV HSC NEW ORLEANS	MODERATE ALCOHOL USE—CARDIOVASCULAR RISKS AND BENEFITS	243,652
R01AA011760–05	MASON, CAROL M	LOUISIANA STATE UNIV HSC NEW ORLEANS	ALCOHOL, TB AND AIDS	184,376
R01AA012865–01	KASTIN, ABBA J	TULANE UNIVERSITY OF LOUISIANA	PEPTIDES AND ALCOHOL INTERACT AT THE BLOOD–BRAIN BARRIER	214,000
R01AG016592–02	BERENSON, GERALD S.	TULANE UNIVERSITY OF LOUISIANA	EVOLUTION OF CARDIOVASCULAR RISK WITH NORMAL AGING	713,391
R01AG017887–02	JAZWINSKI, S MICHAL	LOUISIANA STATE UNIV HSC NEW ORLEANS	NUTRITIONAL AND METABOLIC MECHANISMS OF AGING	336,000
R01AG017981–02	MCLAUGHLIN, MARK L	LOUISIANA STATE UNIV A&M COL BATON ROUGE	BETA-SHEET MIMICS FROM CONSTRAINED DIPEPTIDE UNITS	182,340
R01AG017983–02	HAMMER, ROBERT P	LOUISIANA STATE UNIV A&M COL BATON ROUGE	INHIBITION OF FIBRILLOGENESIS WITH B–STRAND MIMICS	291,180
R01AG018031–01A1	LUKIW, WALTER J	LOUISIANA STATE UNIV HSC NEW ORLEANS	Gene Expression in Alzheimer's Disease	237,738
R01AG018239–02	GEISELMAN, PAULA J	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	OBESITY PREVENTION AFTER SMOKING CESSATION IN MENOPAUSE	183,749
R01AG018648–02	VANLANDINGHAM, MARK J	TULANE UNIVERSITY OF LOUISIANA	SOCIO-DEMOGRAPHIC IMPACT OF AIDS ON OLDER PERSONS	111,375
R01AG018648–02S1	VANLANDINGHAM, MARK J	TULANE UNIVERSITY OF LOUISIANA	SOCIO-DEMOGRAPHIC IMPACT OF AIDS ON OLDER PERSONS	55,688
R01AG018869–01	SUITOR, JILL J	LOUISIANA STATE UNIV A&M COL BATON ROUGE	PARENT-ADULT CHILD RELATIONS: WITHIN FAMILY DIFFERENCES	545,893
R01AG018869–01S1	SUITOR, JILL J	LOUISIANA STATE UNIV A&M COL BATON ROUGE	PARENT-ADULT CHILD RELATIONS: WITHIN FAMILY DIFFERENCES	29,106
R01AI022001–17	O'CALLAGHAN, DENNIS J	LOUISIANA STATE UNIV HSC SHREVEPORT	NUCLEIC ACIDS OF HERPES VIRUS INFECTED CELLS	336,305
R01AI024030–14	Robinson, JAMES E	TULANE UNIVERSITY OF LOUISIANA	HIV–1 Neutralizing Human MAbs	309,163
R01AI031567–07	CHERVENAK, ROBERT P	LOUISIANA STATE UNIV HSC SHREVEPORT	DEVELOPMENTAL BIOLOGY OF T CELL PRECURSORS	183,440
R01AI032556–07	FIDEL, PAUL L	LOUISIANA STATE UNIV HSC NEW ORLEANS	MUCOSAL CELL MEDIATED IMMUNITY IN VAGINAL CANDIDIASIS	214,500
R01AI033325–10	KHAN, IMTIAZ A	LOUISIANA STATE UNIV HSC NEW ORLEANS	LONG TERM IMMUNITY AGAINST TOXOPLASMOSIS	258,541
R01AI040667–06	VAN DER HEYDE, HENRI C	LOUISIANA STATE UNIV HSC SHREVEPORT	Cell adhesion molecules in cerebral malaria.	253,750
R01AI040690–03	QUAYLE, ALISON J.	LOUISIANA STATE UNIV HSC NEW ORLEANS	HUMAN DEFENSIN–5 IN FEMALE GENITAL TRACT IMMUNE DEFENSE	142,804
R01AI042146–03	MUGGERIDGE, MARTIN I	LOUISIANA STATE UNIV HSC SHREVEPORT	ROLES OF HSV2 MEMBRANE PROTEINS IN MEMBRANE FUSION	180,021
R01AI042400–02	DAVISON, BILLIE B	TULANE UNIVERSITY OF LOUISIANA	A RHESUS MONKEY MODEL OF MALARIA IN PREGNANCY	454,121
R01AI042777–04	CLEMENTS, JOHN D	TULANE UNIVERSITY OF LOUISIANA	MECHANISM OF CHOLERA TOXIN AND E COLI LT ADJUVANTICITY	201,345
R01AI043000–03	KOUSOULAS, KONSTANTIN GUS	LOUISIANA STATE UNIV A&M COL BATON ROUGE	GENETICS & FUNCTIONS OF HSV1 GK IN VIRUS ENTRY & EGRESS	289,052
R01AI043693–05	KHAN, IMTIAZ A	LOUISIANA STATE UNIV HSC NEW ORLEANS	ENCEPHALITOZOAN CUNICULI—HOST IMMUNITY AND PATHOGENESIS	221,460
R01AI045041–03	HURLBURT, BARRY K	U.S. AGRICULTURE RESEARCH SERVICE–MIDSOU	MECHANISMS OF VIRULENCE GENE REGULATION IN S. AUREUS	180,762
R01AI045151–02	FREYTAG, LUCIA C	TULANE UNIVERSITY OF LOUISIANA	MUCOSAL IMMUNIZATION—PREVENTION OF SYSTEMIC CANDIDIASIS	222,750
R01AI045725–02	GILLIS, THOMAS P	NATIONAL HANSEN'S DISEASE PROGRAM	DEVELOP AND EVALUATE NEW LEPROSY AND TB VACCINES	113,583
R01AI046275–03	Robinson, JAMES E	TULANE UNIVERSITY OF LOUISIANA	RHESUS MABS FROM SHIV INFECTED MACAQUES	227,232
R01AI049080–01A1	VEAZEY, RONALD S	TULANE UNIVERSITY OF LOUISIANA	Mechanisms of CD4 Depletion and Proliferation in SIV	400,000
R01AI049139–01A1	OBERHELMAN, RICHARD A	TULANE UNIVERSITY OF LOUISIANA	Diagnostics for AIDS–Related Pediatric TB, Peru	266,110
R01AI049976–01	PHILIPP, MARIO T	TULANE UNIVERSITY OF LOUISIANA	'Lyme disease: A possible test for cure	152,000
R01AR045982–04	ALA–KOKKA, LEENA M	TULANE UNIVERSITY OF LOUISIANA	MUTATIONS CAUSING DISC DISEASE AND SCIATICA	281,321
R01AR046976–03	KIMPEL, DONALD L	LOUISIANA STATE UNIV HSC SHREVEPORT	NOVEL IMAGING TECHNOLOGIES FOR RHEUMATOID ARTHRITIS	290,000
R01AR048323–01	PROCKOP, DARWIN J	TULANE UNIVERSITY OF LOUISIANA	Osteoprogenitors for Potential Therapy of OI	371,250
R01CA054152–09S1	HILL, STEVEN M	TULANE UNIVERSITY OF LOUISIANA	NEUROENDOCRINE INFLUENCES ON MAMMARY CANCER	37,431
R01CA065600–05	JETER, JAMES R	TULANE UNIVERSITY OF LOUISIANA	CARCINOGENESIS AND LOSS OF DIFFERENTIATION CONTROL	178,547
R01CA067372–07	SIXBEY, JOHN W.	LOUISIANA STATE UNIV HSC SHREVEPORT	Epstein Barr Virus Induced Genomic Instability	326,250
R01CA075613–03	HWANG, DANIEL H	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	CYCLOOXYGENASE AND TUMORIGENESIS	191,184
R01CA078335–03	GNARRA, JAMES R	LOUISIANA STATE UNIV HSC NEW ORLEANS	HGF/SF SIGNALING BY THE VHL TUMOR SUPPRESSOR	214,314

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
R01CA078335–03S1	GNARRA, JAMES R	LOUISIANA STATE UNIV HSC NEW ORLEANS	HGF/SF SIGNALING BY THE VHL TUMOR SUPPRESSOR	72,221
R01CA080149–03	MATHIS, J MICHAEL	LOUISIANA STATE UNIV HSC SHREVEPORT	ADENOVIRUS BASED P53 GENE THERAPY FOR OVARIAN CANCER	111,193
R01CA081125–03	SCHWARZENBERGER, PAUL O	LOUISIANA STATE UNIV HSC NEW ORLEANS	IL–17 AND HEMATOPOIESIS	139,863
R01CA081506–02	EHRLICH, MELANIE	TULANE UNIVERSITY OF LOUISIANA	DNA HYPOMETHYLATION AND CANCER	251,510
R01CA082689–03	OCHOA, AUGUSTO C.	LOUISIANA STATE UNIV HSC NEW ORLEANS	INDUCTION OF ANERGY AND ALTERED SIGNAL TRANSDUCTION	207,865
R01CA083823–02	Levy, Laura S.	TULANE UNIVERSITY OF LOUISIANA	SELECTIVE FORCES OPERATIVE IN FELV INFECTION	248,883
R01CA085693–02	HARRISON, LYNN	LOUISIANA STATE UNIV HSC SHREVEPORT	DNA REPAIR OF MULTIPLY DAMAGED SITES IN CELLS	195,750
R01CA088885–01	OCHOA, AUGUSTO C.	LOUISIANA STATE UNIV HSC NEW ORLEANS	IMMUNE DYSFUNCTION AND IMMUNOTHERAPY OF RENAL CANCER	288,024
R01CA089057–01A1	LI, LI	OCHSNER CLINIC FOUNDATION	Stromal Cell Molecules Required for Lymphoma Generation	166,250
R01CA089121–01A1	Dash, Srikanta A.	TULANE UNIVERSITY OF LOUISIANA	Hepatitis C Virus and Hepatocellular Carcinoma	233,888
R01CA095783–01	JONES, FRANK E	TULANE UNIVERSITY OF LOUISIANA	ErbB4 signaling in the normal and neoplastic breast	234,226
R01DA005084–14	LINDBERG, IRIS	LOUISIANA STATE UNIV HSC NEW ORLEANS	OPIOID PEPTIDE SYNTHESIZING ENZYMES	180,316
R01DA006013–09	GOEDERS, NICHOLAS E	LOUISIANA STATE UNIV HSC SHREVEPORT	ENVIRONMENTAL INFLUENCES ON COCAINE SELF ADMINISTRATION	213,738
R01DA009820–06	GLOWA, JOHN R	LOUISIANA STATE UNIV HSC SHREVEPORT	DETERMINANTS OF DRUG EFFECTS ON DRUG MAINTAINED BEHAVIOR	387,962
R01DA011417–03	Moerschbaecher, Joseph M.	LOUISIANA STATE UNIV HSC NEW ORLEANS	CANNABINOID ABUSE EFFECTS ON LEARNING AND MEMORY	194,804
R01DA011417–03S1	Moerschbaecher, Joseph M.	LOUISIANA STATE UNIV HSC NEW ORLEANS	CANNABINOID ABUSE EFFECTS ON LEARNING AND MEMORY	31,460
R01DA011528–05	TRUDELL, MARK L	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	SYNTHESIS OF POTENTIAL COCAINE ABUSE THERAPEUTICS	257,932
R01DA011939–02	Harlan, Richard E	TULANE UNIVERSITY OF LOUISIANA	THALAMOSTRIATAL MECHANISMS OF MORPHINE ACTION	174,238
R01DA012267–03	HARRISON, MURELLE G	SOUTHERN UNIV A&M COL BATON ROUGE	PREVENTING SUBSTANCE USE IN RURAL AFRICAN–AMERICAN YOUTH	598,668
R01DA012267–03S1	HARRISON, MURELLE G	SOUTHERN UNIV A&M COL BATON ROUGE	PREVENTING SUBSTANCE USE IN RURAL AFRICAN–AMERICAN YOUTH	13,825
R01DA012427–02	WINSAUER, PETER J	LOUISIANA STATE UNIV HSC NEW ORLEANS	COCAINE SELF-ADMINSTRATION: EFFECTS ON LEARNING	97,643
R01DA012703–03	TRUDELL, MARK L	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	NOVEL NICOTINIC RECEPTOR MEDIATED THERAPEUTIC AGENTS	285,517
R01DA013463–01A1	GOEDERS, NICHOLAS E	LOUISIANA STATE UNIV HSC SHREVEPORT	Role for the HPA Axis in Methamphetamine Reinforcement	310,794
R01DA013470–01A1	STEKETEE, JEFFERY D	LOUISIANA STATE UNIV HSC SHREVEPORT	Medial Prefrontal Cortex and Cocaine Sensitization	53,717
R01DA013899–01A1	MORSE, EDWARD V	TULANE UNIVERSITY OF LOUISIANA	Risk Reduction for Young African American IDUs	562,493
R01DC003679–03	Hood, Linda Jean	LOUISIANA STATE UNIV HSC NEW ORLEANS	AUDITORY GENETIC STUDIES OF HEREDITARY HEARING LOSS	207,374
R01DC003792–03	CAPRIO, JOHN T	LOUISIANA STATE UNIV A&M COL BATON ROUGE	ENCODING OF BIOLOGICALLY RELEVANT ODOR SIGNALS	319,975
R01DC003896–03	Ricci, Anthony J	LOUISIANA STATE UNIV HSC NEW ORLEANS	ENDOGENOUS FACTORS REGULATING TRANSDUCER ADAPTATION	166,126
R01DC004196–03	Keats, Bronya J.	LOUISIANA STATE UNIV HSC NEW ORLEANS	ID OF THE MOUSE DEAFNESS (DN) GENE ON CHROMOSOME 19	224,047
R01DE008911–10	WISE, GARY E	LOUISIANA STATE UNIV A&M COL BATON ROUGE	MOLECULAR BASIS OF TOOTH ERUPTION	173,814
R01DE012178–04	FIDEL, PAUL L	LOUISIANA STATE UNIV HSC NEW ORLEANS	ORAL IMMUNE DYSFUNCTION AND CANDIDIASIS IN HIV INFECTION	
R01DE012178–04S1	FIDEL, PAUL L	LOUISIANA STATE UNIV HSC NEW ORLEANS	ORAL IMMUNE DYSFUNCTION AND CANDIDIASIS IN HIV INFECTION	108,940
R01DE012178–04S2	FIDEL, PAUL L	LOUISIANA STATE UNIV HSC NEW ORLEANS	ORAL IMMUNE DYSFUNCTION AND CANDIDIASIS IN HIV INFECTION	26,240
R01DE012329–03	CHEN, YIPING	TULANE UNIVERSITY OF LOUISIANA	MOLECULAR MECHANISMS OF VERTEBRATE TOOTH INITIATION	180,242
R01DE012916–03	AMEDEE, ANGELA M	LOUISIANA STATE UNIV HSC NEW ORLEANS	SIV MACAQUE MODEL FOR BREAST MILK TRANSMISSION OF HIV	317,085
R01DK039232–12	CARDELLI, JAMES A	LOUISIANA STATE UNIV HSC SHREVEPORT	REGULATION OF PHAGOCYTOSIS	185,261
R01DK041279–09A2	GLASS, JONATHAN D	LOUISIANA STATE UNIV HSC SHREVEPORT	Molecular Mechanisms of Intestinal Iron Transport	246,500
R01DK041868–11	HWANG, DANIEL H	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	DIETARY N 3 FATTY ACIDS AND EXPRESSION OF CYCLOOXYGENASE	191,169

R01DK042714–10	HORNBY, PAMELA J	LOUISIANA STATE UNIV HSC NEW ORLEANS	CNS AUTONOMIC PATHWAYS AND GASTROINTESTINAL FUNCTION	182,394
R01DK043337–09	KAPUSTA, DANIEL R	LOUISIANA STATE UNIV HSC NEW ORLEANS	OPIOIDS AND CENTRAL NEURAL REGULATION OF RENAL FUNCTION	146,731
R01DK044510–08	AW, TAK Y	LOUISIANA STATE UNIV HSC SHREVEPORT	Glutathione redox control of intestinal cell responses	261,000
R01DK045278–09	York, David A.	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	ENTEROSTATIN REGULATION OF FAT INTAKE	321,528
R01DK046935–07	Lancaster, Jack R.	LOUISIANA STATE UNIV HSC NEW ORLEANS	NITROGEN AND OXYGEN RADICAL INTERACTIONS IN SURGERY	198,912
R01DK046935–07S1	Lancaster, Jack R.	LOUISIANA STATE UNIV HSC NEW ORLEANS	NITROGEN AND OXYGEN RADICAL INTERACTIONS IN SURGERY	36,886
R01DK047211–07	VEDECKIS, WAYNE V.	LOUISIANA STATE UNIV HSC NEW ORLEANS	REGULATION OF GLUCOCORTICOID RECEPTOR GENE EXPRESSION	180,596
R01DK047348–08	BERTHOUD, HANS–RUDOLF	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	AUTONOMIC REGULATION OF FOOD INTAKE AND METABOLISM	179,844
R01DK047663–07	GRISHAM, MATTHEW B	LOUISIANA STATE UNIV HSC SHREVEPORT	ADHESION MOLECULE EXPRESSION IN CHRONIC GUT INFLAMMATION	177,703
R01DK048055–06A2	MCCARTHY, KEVIN J.	LOUISIANA STATE UNIV HSC SHREVEPORT	Proteoglycans in Diabetic Nephropathy	290,000
R01DK049703–05S3	LINDBERG, IRIS	LOUISIANA STATE UNIV HSC NEW ORLEANS	CONTROL OF PEPTIDE HORMONE BIOSYNTHESIS BY PC2 AND 7B2	71,500
R01DK052968–03	Stephens, Jacqueline M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	REGULATION AND ACTIVATION OF STATS IN ADIPOCYTES	185,448
R01DK053113–03	SMITH, BRENDA K	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	TASTE AND GENETIC MECHANISMS OF MACRONUTRIENT SELECTION	216,418
R01DK053697–04S1	CORREA, PELAYO	LOUISIANA STATE UNIV HSC NEW ORLEANS	HELICOBACTER INFECTION AND GROWTH OF CHILDREN	25,000
R01DK053697–05	CORREA, PELAYO	LOUISIANA STATE UNIV HSC NEW ORLEANS	HELICOBACTER INFECTION AND GROWTH OF CHILDREN	46,225
R01DK053981–04	GETTYS, THOMAS W	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	MECHANISMS OF UCP REGULATION BY LEPTIN	198,992
R01DK054880–03	KASTIN, ABBA J	TULANE UNIVERSITY OF LOUISIANA	BLOOD/BRAIN BARRIER AND LEPTIN TRANSPORT IN OBESITY	321,158
R01DK054952–02	HAMM, L. LEE	TULANE UNIVERSITY OF LOUISIANA	REGULATION OF CITRATE TRANSPORT	198,450
R01DK055626–02	AWAYDA, MOUHAMED S.	TULANE UNIVERSITY OF LOUISIANA	KINASE REGULATION OF THE EPITHELIAL NA CHANNEL	222,750
R01DK056132–01A2	SMITH, BRET N	TULANE UNIVERSITY OF LOUISIANA	Neural Circuitry in the Caudal Solitary Complex	297,750
R01DK056264–02	El-Dahr, Samir S.	TULANE UNIVERSITY OF LOUISIANA	INDUCIBLE DYSPLASTIC NEPHROPATHY IN B2-DEFICENT MICE	267,300
R01DK057242–02	BERTHOUD, HANS–RUDOLF	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	FUNCTIONAL ORGANIZATION OF THE VAGAL–ENTERIC INTERFACE	209,153
R01DK057446–03	LOVEJOY, JENNIFER C	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	INTERNET–AIDED PREVENTION OF PREGNANCY–INDUCED OBESITY	141,699
R01DK057476–03	MARTIN, PAMELA D	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	PRIMARY CARE OFFICE MANAGEMENT OF OBESITY	186,088
R01DK058152–02	KOZAK, LESLIE P	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	GENETICS OF DEVELOPMENTAL PLASTICITY IN THE ADIPOCYTE	432,199
R01DK058499–01A1	AGRAWAL, KRISHNA C	TULANE UNIVERSITY OF LOUISIANA	Protease Inhibitor Related Adipogenesis in HIV Infection	282,150
R01DK060412–01	RAVUSSIN, ERIC	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	Fat Cell Size, Muscle Lipid and Insulin Resistance	613,281
R01ES006766–08	Brody, Arnold R	TULANE UNIVERSITY OF LOUISIANA	GROWTH FACTORS IN ASBESTOS INDUCED PULMONARY FIBROSIS	250,931
R01ES008663–05	FRIEDMAN, MITCHELL	TULANE UNIVERSITY OF LOUISIANA	BIOCHEMICAL MECHANISM FOR OZONE PATHOLOGY	193,757
R01ES009158–05	PRUETT, STEPHEN B	LOUISIANA STATE UNIV HSC SHREVEPORT	Mechanisms of Immunotoxcity of Chemical Stressors	205,350
R01ES009870–02	MEHENDALE, HARIHARA M	UNIVERSITY OF LOUISIANA AT MONROE	DIETARY RESTRICTION AND TOXICANT–INDUCED LIVER DISEASE	248,832
R01ES010046–02	LASKY, JOSEPH A	TULANE UNIVERSITY OF LOUISIANA	DISRUPTION OF PDGF SIGNAL TRANSDUCTION IN LUNG FIBROSIS	222,750
R01EY002672–23	KAUFMAN, HERBERT E	LOUISIANA STATE UNIV HSC NEW ORLEANS	OCULAR HERPES SIMPLEX VIRUS	346,750
R01EY003311–22	KLYCE, STEPHEN D	LOUISIANA STATE UNIV HSC NEW ORLEANS	INTEGRATED ASSESSMENT OF CORNEAL FORM AND FUNCTION	259,731
R01EY004928–19	BAZAN, HAYDEE E	LOUISIANA STATE UNIV HSC NEW ORLEANS	CORNEAL LIPID METABOLISM AND RESPONSE TO INFLAMMATION	197,171
R01EY005121–17A1	BAZAN, NICOLAS G	LOUISIANA STATE UNIV HSC NEW ORLEANS	RPE Messengers, Transcription and Photoreceptor Renewal	250,250
R01EY006311–15	HILL, JAMES M	LOUISIANA STATE UNIV HSC NEW ORLEANS	OCULAR HSV—LATENCY, REACTIVATION, AND RECURRENCE	121,399
R01EY006311–16	HILL, JAMES M	LOUISIANA STATE UNIV HSC NEW ORLEANS	Ocular HSV—Latency, Reactivation, and Recurrence	160,875
R01EY006635–15	BAZAN, HAYDEE E	LOUISIANA STATE UNIV HSC NEW ORLEANS	CELL SIGNAL TRANSDUCTION IN CORNEAL WOUND HEALING	223,276
R01EY007380–12	MENERAY, MICHELE A	LOUISIANA STATE UNIV HSC NEW ORLEANS	INTERACTIVE CELLULAR CONTROLS LACRIMAL GLAND FUNCTIONAL	286,000

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
R01EY008871–11	HILL, JAMES M	LOUISIANA STATE UNIV HSC NEW ORLEANS	OCULAR PATHOGENESIS AND THERAPY OF BACTERIAL KERATITIS	301,534
R01EY010974–06	O'CALLAGHAN, RICHARD J	LOUISIANA STATE UNIV HSC NEW ORLEANS	STAPH KERATITIS—MECHANISMS/ARRESTING OF CORNEAL DAMAGE	257,394
R01EY011610–04	BURGOYNE, CLAUDE F	LOUISIANA STATE UNIV HSC NEW ORLEANS	IOP RELATED FORCE AND FAILURE IN THE OPTIC NERVE HEAD	328,054
R01EY012367–03	JACOB, JEAN T	LOUISIANA STATE UNIV HSC NEW ORLEANS	EPITHELIALIZATION OF TISSUE ENGINEERED CORNEAS	503,786
R01EY012416–03	BEUERMAN, ROGER W	LOUISIANA STATE UNIV HSC NEW ORLEANS	REGULATION OF PROTEIN SYNTHESIS IN THE LACRIMAL GLAND	218,284
R01EY012540–03	PALKAMA, ARTO K	LOUISIANA STATE UNIV HSC NEW ORLEANS	AQUEOUS OUTFLOW AND STRUCTURAL CORRELATIONS	337,419
R01EY012701–02	CHANDRASEKHER, GUDISEVA	LOUISIANA STATE UNIV HSC NEW ORLEANS	GROWTH FACTOR RECEPTOR MEDITATED SIGNAL MECHANISMS LENS	175,955
R01EY012716–01A2	GUIDO, WILLIAM	LOUISIANA STATE UNIV HSC NEW ORLEANS	FUNCTIONAL STATE OF DEVELOPING RETINOGENICULATE SYNAPSE	204,137
R01EY012887–02	KHOOBEHI, BAHRAM	LOUISIANA STATE UNIV HSC NEW ORLEANS	RETINAL AND CHOROIDAL BLOOD FLOW IMAGING	223,146
R01EY012961–02	O'CALLAGHAN, RICHARD J	LOUISIANA STATE UNIV HSC NEW ORLEANS	MECHANISMS AND THERAPY OF BACTERIAL KERATITIS	286,000
R01GM020818–27S1	RHOADS, ROBERT E.	LOUISIANA STATE UNIV HSC SHREVEPORT	REGULATION OF EUKARYOTIC PROTEIN SYNTHESIS INITITATION	94,237
R01GM039844–11	WARNER, ISIAH M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	Bioanalytical Separation Using Chiral Polymers	351,000
R01GM039844–11S1	WARNER, ISIAH M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	Bioanalytical Separation Using Chiral Polymers	15,817
R01GM045668–09	DEININGER, Prescott L	TULANE UNIVERSITY OF LOUISIANA	HUMAN DIMORPHISMS BY SINE MASTER GENES	241,319
R01GM047789–17	TATCHELL, Kelly G.	LOUISIANA STATE UNIV HSC SHREVEPORT	GENETIC ANALYSIS OF PROTEIN PHOSPHATASE 1 IN YEAST	279,098
R01GM048045–10	FLEMINGTON, ERIK K.	TULANE UNIVERSITY OF LOUISIANA	EBV BZLF1 GENE PRODUCT	239,669
R01GM051261–05	WALDROP, GROVER L	LOUISIANA STATE UNIV A&M COL BATON ROUGE	CATALYTIC MECHANISM OF BIOTIN DEPENDENT ENZYMES	95,162
R01GM051521–08	WITT, STEPHEN N.	LOUISIANA STATE UNIV HSC SHREVEPORT	KINETICS AND MECHANISM OF THE HEAT SHOCK 70 PROTEIN DNAK	199,697
R01GM055420–11	NEWCOMER, MARCIA E.	LOUISIANA STATE UNIV A&M COL BATON ROUGE	ENZYMATIC ACTIVATION OF LIPOPHILIC SIGNALING MOLECULES	71,473
R01GM056835–04	MCLAUGHLIN, MARK L	LOUISIANA STATE UNIV A&M COL BATON ROUGE	PEPTIDES ACTIVE AGAINST INTRACELLULAR PATHOGENIC DISEASE	171,443
R01GM058843–03	LIMBACH, PATRICK A.	LOUISIANA STATE UNIV A&M COL BATON ROUGE	IDENTIFICATION OF MODIFIED NUCLEOSIDES IN RIBOSOMAL RNA	130,415
R01GM059663–01A2	WITTUNG–STAFSHEDE, PERNILLA E	TULANE UNIVERSITY OF LOUISIANA	COFACTOR ROLE IN BETA-SHEET PROTEIN FOLDING	157,180
R01GM060000–01A2	WIMLEY, WILLIAM C	TULANE UNIVERSITY OF LOUISIANA	Folding and design of beta sheets in membranes	173,500
R01GM061915–01A1	STRONGIN, ROBERT M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	Synthesis and Study of Novel Sensing Agents	183,750
R01HD008431–26	KOZAK, LESLIE P	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	MOLECULAR GENETICS OF THERMOGENESIS	311,940
R01HD036822–03	WANG, YU–PING	LOUISIANA STATE UNIV HSC SHREVEPORT	PLACENTAL FUNCTION IN PREECLAMPSIA	141,187
R01HD037811–02	GASSER, RAYMOND F	LOUISIANA STATE UNIV HSC NEW ORLEANS	HUMAN EMBRYO SECTIONS ON COMPUTER DISKS FOR EDUCATION	244,821
R01HD039104–02	WILLIAMSON, DONALD A.	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	INTERNET–BASED OBESITY PREVENTION FOR BLACK ADOLESCENTS	158,490
R01HG001499–05	SOPER, Steven A	LOUISIANA STATE UNIV A&M COL BATON ROUGE	HIGH THROUGHPUT DNA SEQUENCING USING NANO-REACTORS	393,493
R01HG001499–05S1	SOPER, Steven A	LOUISIANA STATE UNIV A&M COL BATON ROUGE	HIGH THROUGHPUT DNA SEQUENCING USING NANO-REACTORS	31,605
R01HL026371–20	Navar, L. Gabriel	TULANE UNIVERSITY OF LOUISIANA	RENAL FUNCTIONAL DERANGEMENTS IN HYPERTENSION	327,703
R01HL026441–21	GRANGER, D NEIL	LOUISIANA STATE UNIV HSC SHREVEPORT	TRANSCAPILLARY FLUID EXCHANGE	249,045
R01HL045670–10	BOUCHARD, CLAUDE	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	HERITAGE–GENETICS, RESPONSE TO EXERCISE, RISK FACTORS–3	723,661
R01HL054797–08	KORTHUIS, RONALD J	LOUISIANA STATE UNIV HSC SHREVEPORT	PRECONDITIONING: PMN ADHESION AND MICROVASCULAR INJURY	290,000
R01HL059699–04	IMIG, JOHN D	TULANE UNIVERSITY OF LOUISIANA	OXYGENASE METABOLITES AND RENAL VASCULAR ACTIVITY	27,519
R01HL059699–05	IMIG, JOHN D	TULANE UNIVERSITY OF LOUISIANA	OXYGENASE METABOLITES AND RENAL VASCULAR ACTIVITY	69,000
R01HL059724–05	SHELLITO, JUDD E	LOUISIANA STATE UNIV HSC NEW ORLEANS	T LYMPHOCYTE SUBSETS AND HOST DEFENSE AGAINST P CARINII	357,165
R01HL059879–03	CLAYCOMB, WILLIAM C	LOUISIANA STATE UNIV HSC NEW ORLEANS	NOVEL GENE DISCOVERED IN THE HEART	213,150

R01HL060300–05	HE, JIANG	TULANE UNIVERSITY OF LOUISIANA	EPIDEMIOLOGY STUDIES OF DIETARY FIBER AND BLOOD PRESSURE	104,421
R01HL060532–05	Brody, Arnold R	TULANE UNIVERSITY OF LOUISIANA	EPITHELIAL GROWTH FACTORS IN ENVIRONMENTAL LUNG DISEASE	285,524
R01HL060849–03	LEFER, DAVID J	LOUISIANA STATE UNIV HSC SHREVEPORT	MECHANISMS OF MYOCARDIAL REPERFUSION INJURY--DIABETES	180,586
R01HL061271–03	Kolls, Jay K.	LOUISIANA STATE UNIV HSC NEW ORLEANS	NON CD4 HOST DEFENSE AGAINST P CARINII PNEUMONIA	76,076
R01HL061934–05	MORRIS, CINDY A	TULANE UNIVERSITY OF LOUISIANA	MOLECULAR MECHANISM OF TAT INDUCED ANGIOGENESIS	222,750
R01HL062000–01A2S1	HYMAN, ALBERT L	TULANE UNIVERSITY OF LOUISIANA	CARDIOPULMONARY SURGERY RESEARCH	43,065
R01HL062000–02	HYMAN, ALBERT L	TULANE UNIVERSITY OF LOUISIANA	CARDIOPULMONARY SURGERY RESEARCH	302,940
R01HL062052–03S1	Kolls, Jay K.	LOUISIANA STATE UNIV HSC NEW ORLEANS	CD8 AND GAMMA/DELTA T CELLS IN P CARINII PNEUMONIA	4,976
R01HL062052–04	Kolls, Jay K.	LOUISIANA STATE UNIV HSC NEW ORLEANS	CD8 AND GAMMA/DELTA T CELLS IN P CARINII PNEUMONIA	255,226
R01HL062052–04S1	Kolls, Jay K.	LOUISIANA STATE UNIV HSC NEW ORLEANS	CD8 AND GAMMA/DELTA T CELLS IN P CARINII PNEUMONIA	4,976
R01HL062147–04	PANDEY, KAILASH N	TULANE UNIVERSITY OF LOUISIANA	ANP RECEPTOR GENE--TARGETING AND EXPRESSION	160,386
R01HL063128–02	AGRAWAL, KRISHNA C	TULANE UNIVERSITY OF LOUISIANA	MECHANISMS OF CARDIOVASCULAR COMPLICATIONS IN AIDS	291,666
R01HL063195–03	TRAYANOVA, NATALIA A	TULANE UNIVERSITY OF LOUISIANA	CARDIAC TISSUE STRUCTURE IN THE DEFIBRILLATION PROCESS	165,539
R01HL063778–01A1	LASKY, JOSEPH A	TULANE UNIVERSITY OF LOUISIANA	CTGF IN LUNG FIBROGENESIS	253,813
R01HL064555–03	CLARKSON, CRAIG W	TULANE UNIVERSITY OF LOUISIANA	MOLECULAR BASIS FOR DRUG INDUCED CARDIOTOXICITY IN AIDS	189,054
R01HL064577–03	JOHNSON, ROBERT A	TULANE UNIVERSITY OF LOUISIANA	HEMODYNAMIC ROLES OF ENDOGENEOUS CARBON MONOXIDE	167,296
R01HL065997–01	WANG, YU–PING	LOUISIANA STATE UNIV HSC SHREVEPORT	ENDOTHELIAL BARRIER FUNCTION IN PREECLAMPSIA	242,500
R01HL066158–01A1	VEHASKARI, V M	LOUISIANA STATE UNIV HSC NEW ORLEANS	Prenatal and Perinatal Programming of Adult Hypertension	239,500
R01HL066432–01A1	MAJID, DEWAN S	TULANE UNIVERSITY OF LOUISIANA	Superoxide and nitric Oxide Interactions in the Kidney	247,750
R01NS009626–31	LI, YU–TEH	TULANE UNIVERSITY OF LOUISIANA	GLYCOSIDASES AS RELATED TO SPHINGOLIPIDOSES	344,502
R01NS009626–31S1	LI, YU–TEH	TULANE UNIVERSITY OF LOUISIANA	GLYCOSIDASES AS RELATED TO SPHINGOLIPIDOSES	27,716
R01NS025134–12	HAYCOCK, JOHN W	LOUISIANA STATE UNIV HSC NEW ORLEANS	CELLULAR REGULATION OF TYROSINE HYDROXYLASE	214,604
R01NS025987–14	PHELPS, CAROL J.	TULANE UNIVERSITY OF LOUISIANA	HYPOPHYSIOTROPIC NEURON DIFFERENTIATION--TARGET FEEDBACK	213,375
R01NS035370–09A1	DUNN, ADRIAN J	LOUISIANA STATE UNIV HSC SHREVEPORT	Cytokine Action on the CNS	283,070
R01NS036936–04	ERICKSON, JEFFREY D	LOUISIANA STATE UNIV HSC NEW ORLEANS	VESICULAR TRANSPORTER SPECIFICITY	207,749
R01NS037070–04	ERZURUMLU, REHA S	LOUISIANA STATE UNIV HSC NEW ORLEANS	CELLULAR MECHANISMS UNDERLYING PATTERN FORMATION	131,747
R01NS039033–01A2	PHINNEY, DONALD G	TULANE UNIVERSITY OF LOUISIANA	Marrow stromal cells for Lysosomal Disease CNS Defects	259,875
R01NS039050–02	ERZURUMLU, REHA S	LOUISIANA STATE UNIV HSC NEW ORLEANS	SOMATOSENSORY CORTICAL DEVELOPMENT AND PLASTICITY	143,000
R01NS039099–02	TASKER, JEFFREY G	TULANE UNIVERSITY OF LOUISIANA	HYPOTHALAMIC SYNCHRONIZATION BY LOCAL GLUTAMATE CIRCUITS	259,875
R01NS039458–02	MAGEE, JEFFERY C	LOUISIANA STATE UNIV HSC NEW ORLEANS	DENDRITIC INTEGRATION IN HIPPOCAMPAL PYRAMIDAL NEURONS	142,062
R01NS040373–01A1	ARIMURA, AKIRA A	TULANE UNIVERSITY OF LOUISIANA	Neuroprotection by PACAP in Stroke	371,250
R01NS044000–01	BASTIAN, FRANK O	TULANE UNIVERSITY OF LOUISIANA	Spiroplasma 16S rDNA in TSE Brain Tissues	181,745
R03AG019058–01	MEHENDALE, HARIHARA M	UNIVERSITY OF LOUISIANA AT MONROE	AGING AND RESILIENCY TO LIVER TOXICITY	66,844
R03AI043873–03	Pincus, Seth H.	CHILDREN'S HOSPITAL (NEW ORLEANS)	ROLE OF MURINE LEUKEMIA VIRUS IN AUTOIMMUNITY	70,000
R03CA083096–01A1	JOHNSON, ERIC S	TULANE UNIVERSITY OF LOUISIANA	POSSIBLE OF ROLE OF AVIAN RETROVIRUSES IN HUMAN CANCER	71,513
R03CA086378–02	HAGENSEE, MICHAEL E	LOUISIANA STATE UNIV HSC NEW ORLEANS	DEVELOPMENT OF A URINE PCR ASSAY FOR HPV DNA DETECTION	71,500
R03CA088135–02	SU, L. J	LOUISIANA STATE UNIV HSC NEW ORLEANS	DIETARY SURVEY INSTRUMENT DEVELOPMENT FOR AN ETHNIC MINO	69,695
R03DA012547–02	ROERIG, SANDRA C	LOUISIANA STATE UNIV HSC SHREVEPORT	SPINAL NITRIC OXIDE IN CHRONIC INFLAMMATORY PAIN	71,037
R03DA013421–02	LAHOSTE, GERALD J	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	GAP JUNCTIONS AND DOPAMINE PLASTICITY	71,000
R03DA013546–02	HUANG, TIEN L	XAVIER UNIVERSITY OF LOUISIANA	NOVEL ANTI–PCP AGENTS WITH NEUROPROTECTIVE PROPERTIES	69,975

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
R03DA013647–01A1	SMAGIN, GENNADY N	LOUISIANA STATE UNIV HSC SHREVEPORT	NEUROCHEMISTRY OF COCAINE REINFORCEMENT	71,571
R03HD041052–01	SCHMIDT–SOMMERFELD, EBERHARD	LOUISIANA STATE UNIV HSC NEW ORLEANS	PARENTERAL MEDIUM CHAIN TRIGLYCERIDES IN THE PREMATURE	71,500
R03MH061944–02	NORTHUP, JOHN A	LOUISIANA STATE UNIV A&M COL BATON ROUGE	STAR PROGRAM: EARLY & PREVENTIVE INTERVENTION OF ADHD	73,500
R03MH063814–01	SCARAMELLA, LAURA V	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	PARENTING AND TEMPERAMENT RECIPROCITIES IN TODDLERHOOD	71,000
R03MH064587–01	ULLER, CLAUDIA	UNIVERSITY OF LOUISIANA AT LAFAYETTE	MENTAL STATE ATTRIBUTION IN INFANCY	66,720
R13ES011296–01	MCLACHLAN, JOHN A.	TULANE UNIVERSITY OF LOUISIANA CONFERENCE	E.HORMONE 2001	10,000
R15CA086833–01A1	SYLVESTER, PAUL W	UNIVERSITY OF LOUISIANA AT MONROE	ANTIPROLIFERATIVE & APOPTOTIC MECHANISMS OF TOCOTRIENOLS	124,500
R18AI033449–07	FREY, DANIEL J	LOUISIANA ORGAN PROCUREMENT AGENCY	ENHANCING DONOR REGISTRY TO INCREASE DONATION	263,035
R21AR047796–02	PROCKOP, DARWIN J	TULANE UNIVERSITY OF LOUISIANA	EXPANSION OF STEM CELLS FOR SKELETAL TISSUES	74,250
R21CA083198–02	OCHOA, AUGUSTO C.	LOUISIANA STATE UNIV HSC NEW ORLEANS	T CELL SIGNAL TRANSDUCTION TO MONITOR HPV VACCINES	143,000
R21CA084095–02	HYMAN, LINDA E	TULANE UNIVERSITY OF LOUISIANA	ELONGIN C: FUNCTION AND ROLE IN VHL DISEASE	148,500
R21CA091785–02	KEPPLER, DANIEL	LOUISIANA STATE UNIV HSC SHREVEPORT	ROLE OF CYSTATIN M IN BREAST TUMOR PROGRESSION	106,120
R21DC004994–01	BOBBIN, RICHARD P	LOUISIANA STATE UNIV HSC NEW ORLEANS	DRUG MANIPULATION OF NOISE-INDUCED HEARING LOSS	143,000
R21DK057390–01A1	HORNBY, PAMELA J	LOUISIANA STATE UNIV HSC NEW ORLEANS	VAGAL GASTRIC MOTOR CONTROL IN MICE	143,000
R21NS043974–01	EHRLICH, MELANIE	TULANE UNIVERSITY OF LOUISIANA	FSHD SYNDROME—DNA REPEATS, METHYLATION, AND CHROMATIN	185,625
R21RR015016–02	MURRAY, KERMIT K	LOUISIANA STATE UNIV A&M COL BATON ROUGE	MADLI MASS SPECTROMETRY FOR MICROFLUIDIC CHIP DETECTION	99,440
R24CA084625–02	SOPER, STEVEN A	LOUISIANA STATE UNIV A&M COL BATON ROUGE	MICRO-INSTRUMENT PLATFORMS FOR GENETIC-BASED ANALYSES	548,672
R24DA007970–09	KOMISKEY, HAROLD L	XAVIER UNIVERSITY OF LOUISIANA	MIDARP AT XAVIER UNIVERSITY OF LOUISIANA	406,111
R24HL060808–04	STRONG, JACK P	LOUISIANA STATE UNIV HSC NEW ORLEANS	PDAY CARDIOVASCULAR SPECIMEN AND DATA LIBRARY	128,074
R24RR012545–03	BASKIN, GARY B	TULANE UNIVERSITY OF LOUISIANA	ANIMAL MODEL FOR GENE THERAPY OF INHERITED DISORDERS	517,001
R25CA047877–14	LOPEZ S, ALFREDO	LOUISIANA STATE UNIV HSC NEW ORLEANS	SHORT RESEARCH EXPERIENCES IN CANCER	63,347
R25MH058560–04	SAXENA, KRISHAN M	GRAMBLING STATE UNIVERSITY	NIMH HONORS MINORITY HIGH SCHOOL PROGRAM AT GSU	26,001
R29CA076186–04	MEYERS, SHARI L	LOUISIANA STATE UNIV HSC SHREVEPORT	MOLECULAR MECHANISM OF TRANSFORMATION BY AML1/ETO	101,500
R29DC003280–04	GARCIA, MEREDITH M	TULANE UNIVERSITY OF LOUISIANA	PROTEIN KINASE C IN CENTRAL AUDITORY PLASTICITY	100,289
R29DK050151–06	LI, MING	TULANE UNIVERSITY OF LOUISIANA	LVA CALCIUM CHANNEL AND PANCREATIC B CELL DEATH	112,174
R29DK052148–05	KALOGERIS, THEODORE J	LOUISIANA STATE UNIV HSC SHREVEPORT	NEUROHORMONAL CONTROL OF INTESTINAL APOLIPOPROTEIN A IV	99,757
R29ES009055–04	MILLER, CHARLES A	TULANE UNIVERSITY OF LOUISIANA	ARYL HYDROCARBON RECEPTOR STRUCTURE AND INTERACTIONS	91,084
R29EY012204–04	GLEASON, EVANNA L	LOUISIANA STATE UNIV A&M COL BATON ROUGE	METABOTROPIC GLUTAMATE RECEPTORS ON AMACRINE CELLS	99,732
R29HD036310–06	VEAZEY, RONALD S	TULANE UNIVERSITY OF LOUISIANA	ONTOGENY OF THE NEONATAL MACAQUE IMMUNE SYSTEM	118,718
R29HD036421–05	KUBISCH, HANS M	TULANE UNIVERSITY OF LOUISIANA	MARKER ASSISTED SELECTION OF BOVINE BLASTOCYSTS	133,523
R29MH055654–05	FRICK, PAUL J	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	CALLOUS/UNEMOTIONAL TRAITS AND CONDUCT PROBLEMS	86,984
R29NS035865–05	MAGEE, JEFFERY C	LOUISIANA STATE UNIV HSC NEW ORLEANS	DENDRITIC K+ AND IH CHANNELS IN HIPPOCAMPAL NEURONS	106,678
R37AG006168–16	JAZWINSKI, S MICHAL	LOUISIANA STATE UNIV HSC NEW ORLEANS	CELLULAR AGING IN A YEAST MODEL SYSTEM	410,300
R37DK032089–20	BRAY, GEORGE A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	DIETARY OBESITY	300,943
R37DK036013–15	ORLANDO, ROY C	TULANE UNIVERSITY OF LOUISIANA	ESOPHAGEAL CYTOPROTECTION-AGENTS AND MECHANISMS	208,830
R37MH051853–08	MCCANN, SAMUEL M	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	MECHANISM OF ACTION OF CYTOKINES ON BRAIN AND PITUITARY	290,105
R41AG018196–01A1	NARDUCY, KENNETH W	ST CHARLES PHARMACEUTICALS	ANALGESICS FOR CHRONIC PAIN TREATMENT IN THE ELDERLY	100,000
R42CA083756–04	PINCUS, SETH H.	NORION DIAGNOSTIC INNOVATIONS, INC.	HIV INFECTIVITY TEST FOR ANTIVIRAL SUSCEPTIBILITY	141,987

R43CA089772–01	MORGAN, LEE R	DEKK–TEC, INC.	A–007: IMMUNE MODULATION OF HPV—CERVICAL CANCER	191,517
R43CA090123–01	GOTTLIEB, MARISE S	ENDEAVOR CORPORATION	DNA BASED SENSITIVE ASSAY FOR LYMPOID MALIGNANCIES	122,123
R44CA083552–03	MORGAN, LEE R	DEKK–TEC, INC.	ISOPHOSPHORAMIDE MUSTARD—A PHASE 1 STUDY	338,965
R44CA085021–02	MORGAN, LEE R	DEKK–TEC, INC.	DERIVATIVES OF DEMETHYLPENCLOMEDINE: ANTICANCER AGENTS	359,498
S06GM004531–12	IFEANYI, FELIX I	GRAMBLING STATE UNIVERSITY	MBRS SCORE PROGRAM AT GRAMBLING STATE UNIVERSITY	149,473
S06GM008008–30	STEVENS, CHERYL L	XAVIER UNIVERSITY OF LOUISIANA	MBRS SCORE PROGRAM AT XAVIER UNIVERSITY	570,861
S06GM008008–30S1	STEVENS, CHERYL L	XAVIER UNIVERSITY OF LOUISIANA	MBRS SCORE RESEARCH AT XAVIER UNIVERSITY	476,904
S06GM008025–28A1	CHRISTIAN, FRED A	SOUTHERN UNIV A&M COL BATON ROUGE	MBRS SCORE PROGRAM AT SOUTHERN UNIVERSITY-BATON ROUGE	55,505
S11ES009996–03	BLAKE, ROBERT C	XAVIER UNIVERSITY OF LOUISIANA	ALTERATION OF GENE REGULATION BY ENVIRONMENTAL COMPOUNDS	970,632
S11ES010018–03	MUGANDA, PERPETUA M	SOUTHERN UNIV A&M COL BATON ROUGE	CELLULAR & MOLECULAR TOXICOLOGY OF BUTADIENE	906,194
S21MD000100–01	FRANCIS, NORMAN C	XAVIER UNIVERSITY OF LOUISIANA	XAVIER PHARMACY ENDOWMENT FOR MINORITY HEALTH	2,300,000
T32AA007577–03	BAGBY, GREGORY J	LOUISIANA STATE UNIV HSC NEW ORLEANS	BIOMEDICAL ALCOHOL RESEARCH TRAINING PROGRAM	287,988
T32CA065436–05	JAFFE, BERNARD M	TULANE UNIVERSITY OF LOUISIANA	RESEARCH TRAINING IN SURGICAL ONCOLOGY (T32)	26,286
T32DA007311–03	GOEDERS, NICHOLAS E	LOUISIANA STATE UNIV HSC SHREVEPORT	STRESS AND THE NEUROBIOLOGY OF DRUG AND ALCOHOL DEPENDE	282,094
T34GM007716–23	BIRDWHISTELL, TERESA	XAVIER UNIVERSITY OF LOUISIANA	MARC UNDERGRADUATE STUDENT TRAINING IN ACADEMIC RESEARCH	514,676
T34GM008714–03S1	HIMAYA, M A	GRAMBLING STATE UNIVERSITY	U STAR PROGRAM FOR MARC AT GRAMBLING STATE UNIVERSITY	148,110
T34MH017102–19	SAXENA, KRISHAN M	GRAMBLING STATE UNIVERSITY	NIMH COR HONORS UNDERGRADUATE PROGRAM AT GSU	157,376
U01AI032913–09S1	VAN DYKE, RUSSELL B	TULANE UNIVERSITY OF LOUISIANA	TULANE/LSU PEDIATRIC AIDS CLINICAL TRIALS UNIT	884,360
U01AI038844–04S2	LERTORA, JUAN J. L.	TULANE UNIVERSITY OF LOUISIANA	AIDS CLINICAL TRIALS UNIT	318,973
U01AI042178–10	MUSHATT, DAVID M	TULANE UNIVERSITY OF LOUISIANA	LOUISIANA COMMUNITY AIDS RESEARCH PROGRAM (CPCRA)	738,328
U01CA083014–03	ZAKRIS, ELLEN L	TULANE UNIVERSITY OF LOUISIANA	TULANE AIDS–ASSOCIATED MALIGNANCY CONSORTIUM	151,039
U01DK048377–08	BRAY, GEORGE A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	NIDDM PRIMARY PREVENTION TRIAL (DPT 2)	700,258
U01DK056990–03	BRAY, GEORGE A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	CLINICAL CENTER FOR LOOK AHEAD: HEALTH IN DIABETES	1,120,807
U01DK056990–03S1	BRAY, GEORGE A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	CLINICAL CENTER FOR LOOK AHEAD: HEALTH IN DIABETES	7,350
U01DK060963–01	HE, JIANG	TULANE UNIVERSITY OF LOUISIANA	CLINICAL CENTER FOR PROSPECTIVE COHORT STUDY OF CRI	214,285
U01HD031315–08	WILSON, JOHN T	LOUISIANA STATE UNIV HSC SHREVEPORT	PEDIATRIC PHARMACOLOGY RESEARCH UNIT	371,253
U01HD040470–01	ABDALIAN, SUE E	TULANE UNIVERSITY OF LOUISIANA	ADOLESCENT MEDICINE TRIAL NETWORK FOR HIV/AIDS	347,686
U01HL038844–15	BERENSON, GERALD S.	TULANE UNIVERSITY OF LOUISIANA	EARLY NATURAL HISTORY OF ARTERIOSCLEROSIS	1,129,399
U01HL060571–04	HARSHA, DAVID W	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	PREMIER—LIFESTYLE INTERVENE FOR BLOOD PRESSURE CONTRL	344,746
U01HL066855–02	WEBBER, LARRY S.	TULANE UNIVERSITY OF LOUISIANA	TRIAL OF ACTIVITY FOR ADOLESCENT GIRLS (TAAG)	555,628
U10CA035272–18	KARDINAL, CARL G	OCHSNER CLINIC FOUNDATION	OCHSNER COMMUNITY CLINICAL ONCOLOGY PROGRAM	410,631
U10CA058658–09	MILLS, GLENN M	LOUISIANA STATE UNIV HSC SHREVEPORT	SOUTHWEST ONCOLOGY GROUP	283,805
N01HR0R01650–000	DEBOISBLANC, BENNETT	LOUISANA STATE UNIVERSITY BATON ROUGE	ADULT RESPIRATOR DISTRESS SYNDROME STUDY	230,082
U10CA063845–07A1	VEITH, ROBERT W	LOUISIANA STATE UNIV HSC NEW ORLEANS	LSUHSC MINORITY BASED COMMUNITY CLINICAL ONCOLOGY	240,283
U19AI045511–02S1	BEIER, JOHN C	TULANE UNIVERSITY OF LOUISIANA	AFRICAN MALARIA VECTORS	40,000
U19AI045511–03	BEIER, JOHN C	TULANE UNIVERSITY OF LOUISIANA	AFRICAN MALARIA VECTORS	606,005
U42RR015087–02	ROWELL, THOMAS J	UNIVERSITY OF LOUISIANA AT LAFAYETTE	ESTABLISHMENT/MAINTENANCE OF BIOMEDICAL RESEARCH COLONY	819,282
U42RR016026–01	BLANCHARD, JAMES L	TULANE UNIVERSITY OF LOUISIANA	SPECIFIC PATHOGEN FREE INDIAN RHESUS MONKEY COLONY FOR A	725,069
U45ES010664–02	WRIGHT, BEVERLY H	XAVIER UNIVERSITY OF LOUISIANA	WORKER HEALTH AND SAFETY TRAINING COOPERATIVE AGREEMENT	954,135
N01AO012747–000	HASSELSCHWERT, DANA	UNIVERSITY OF LOUISIANA AT LAFAYETTE	DEVELOPMENT OF A SPF PIGTAIL MACAQUE BREEDING COLONY	1,175,750

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
N01NS092302–004	ROWELL, THOMAS J	UNIVERSITY OF LOUISIANA AT LAFAYETTE	SLOW, LATENT & TEMPERATE VIRUS INFECTIONS	615,902
TOTAL FY 2001				85,845,703
FISCAL YEAR 2002				
C06RR016483–01	ROWELL, THOMAS J	UNIVERSITY OF LOUISIANA AT LAFAYETTE	EXPANSION OF NIH CHIMPANZEE HOLDING FAC	1,975,176
D43TW001086–04	MATHER, FRANCES J	TULANE UNIVERSITY OF LOUISIANA	INTERNATIONAL TRAINING IN MEDICAL INFORMATICS	152,358
D43TW001142–04	BEIER, JOHN C	TULANE UNIVERSITY OF LOUISIANA	ACTIONS FOR BUILDING CAPACITY	100,000
F30DA015262–01	KAILAS, SUDHA R	TULANE UNIVERSITY OF LOUISIANA	MORPHINE, SEROTONIN, AND PROTEIN KINASE C	43,075
F31DA005907–03S1	HORNER, KRISTEN A	TULANE UNIVERSITY OF LOUISIANA	CHANGES IN ENDOMORPHINS DURING OPIATE TOLERANCE	3,026
F31DA006040–03	GREENWELL, THOMAS N	TULANE UNIVERSITY OF LOUISIANA	ENDOMORPHIN-NEUROIMMUNE INTERACTIONS	22,895
F31DA014155–02	BANNER, EDITH J	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	TOTAL SYNTHESIS OF NOVEL DECAHYDROQUINOLINES	24,177
F31GM019387–05	HAMILTON, KIMBERLY Y	LOUISIANA STATE UNIV A&M COL BATON ROUGE	CHIRAL SELECTOR IN CAPILLARY ELECTROPHORESIS	24,556
F31GM019876–04	BURSE, JEANINE R	TULANE UNIVERSITY OF LOUISIANA	PAST AND PRESENT BIOINDICATION OF RIVER POLLUTION	6,189
F31GM020437–04	CEDILLO, BERTHA M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	DEVELOPMENT OF A CHIRAL SELECTOR SYSTEM	26,643
F31GM020603–02	WILLIAMS, BRIDGET D	TULANE UNIVERSITY OF LOUISIANA	THE ROLE OF TRACT STABILITY IN TELOMERE MAINTENANCE	20,300
F31GM020915–02	GUTIERREZ, YANIRA I	TULANE UNIVERSITY OF LOUISIANA	PI3K–MEDIATED HYPOXIA SURVIVAL SIGNALING PATHWAYS	22,356
F31GM020928–02	AUSTIN, JOSEPH	LOUISIANA STATE UNIV HSC SHREVEPORT	MINORITY PRE–DOCTORAL FELLOWSHIP PROGRAM	9,226
F31HD041928–01	TRUJILLO, LEA A	TULANE UNIVERSITY OF LOUISIANA	MINORITY PREDOCTORAL FELLOWSHIP PROGRAM	26,160
F31HL068296–02	ANDERSON, KIMBERLY M	TULANE UNIVERSITY OF LOUISIANA	STUDIES OF A NOVEL A AND B BLOOD GROUP CLEAVING ENZYME	22,206
F31MH012816–02	SANTUZZI, ALECIA M	TULANE UNIVERSITY OF LOUISIANA	PREDOCTORAL FELLOWSHIP PROGRAM (DISABILITY)	22,986
F31NS011180–02	CLAYTON BAUCOM, CATHERINE A	TULANE UNIVERSITY OF LOUISIANA	HUMAN HAND PREFERENCE-STRUCTURAL FUNCTIONAL MRI STUDIES	24,176
F32AR048481–01	POCHAMPALLY, RADHIKA R	TULANE UNIVERSITY OF LOUISIANA	MARROW STROMAL CELLS IN OSTEOGENESIS IMPERFECTA MODEL	37,820
F32DA014162–02	DANIEL, JILL M	LOUISIANA STATE UNIV HSC NEW ORLEANS	EFFECTS OF ESTROGEN AND CANNABINOIDS ON LEARNING	38,320
F32DC005284–01A1	LEBLANC, CHRISTOPHER S	LOUISIANA STATE UNIV HSC NEW ORLEANS	HAIR BUNDLE MOVEMENTS AND OTOACOUSTIC EMISSIONS	38,320
F32DK010151–02	WHITE, CHRISTY L	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	LEPTIN RESPONSIVENESS IN A DIETARY MODEL OF OBESITY	50,116
F32DK061137–01	SAIFUDEEN, ZUBAIDA R	TULANE UNIVERSITY OF LOUISIANA	TRANSCRIPTION FACTOR P53 IN TERMINAL NEPHRON DIFFERENT	50,116
F32EY013651–02	MARQUART, MARY E	LOUISIANA STATE UNIV HSC NEW ORLEANS	PSEUDOMONAS PROTEASES AS OCULAR VIRULENCE FACTORS	48,148
F32MH064248–01A1	DAVIS, SCOTT F	TULANE UNIVERSITY OF LOUISIANA	BRAINSTEM CIRCUITS INVOLVED IN ADRENAL REGULATION	38,320
F32MH065092–01A1	BLUMER, JOE B	LOUISIANA STATE UNIV HSC NEW ORLEANS	DEFINING THE ROLE OF AGS3 IN G PROTEIN SIGNAL PROCESSING	38,320
G11HD034961–05	ISLAND, GLENDA J	GRAMBLING STATE UNIVERSITY	GSU RESEARCH INFRASTRUCTURE—PHASE II	91,800
G11HD041839–01	ORBAN, JOSEPH I	SOUTHERN UNIVERSITY SHREVEPORT–BOSSIER	BIOMEDICAL RESEARCH CENTER, SOUTHERN UNIVERSITY AT SHRE	27,000
G20RR017029–01	BLANCHARD, JAMES L	TULANE UNIVERSITY OF LOUISIANA	BUILDING C RENOVATION WEST WING	699,655
K01CA078318–04	HEMENWAY, CHARLES S	TULANE UNIVERSITY OF LOUISIANA	BMI1 INTERACTING PROTEINS IN NEOPLASTIC TRANSFORMATION	140,282
K01ES000358–02	HUNT, JAY D	LOUISIANA STATE UNIV HSC NEW ORLEANS	MUTATION AND ENVIRONMENTAL EXPOSURES	104,372
K01GM000707–03	CHETTY, KOTHAPA N	GRAMBLING STATE UNIVERSITY	HYPERCHOLESTEROLEMIA AND REPERFUSION INJURY	23,994
K02DA000204–10	LINDBERG, IRIS	LOUISIANA STATE UNIV HSC NEW ORLEANS	OPIOID PEPTIDE PROCESSING ENZYMES	118,991
K02DK002605–04	KAPUSTA, DANIEL R	LOUISIANA STATE UNIV HSC NEW ORLEANS	OPIOIDS AND CENTRAL NEURAL REGULATION OF RENAL FUNCTION	100,440

K02MH000967–09	HAYCOCK, JOHN W	LOUISIANA STATE UNIV HSC NEW ORLEANS	HUMAN TYROSINE HYDROXYLASE AND SCHIZOPHRENIA	112,497
K08AI001467–05	MASON, ANDREW L	OCHSNER CLINIC FOUNDATION	RETROVIRAL ETIOLOGY OF PRIMARY BILIARY CIRRHOSIS	118,800
K08AI049790–03	PARADA, NEREIDA A	TULANE UNIVERSITY OF LOUISIANA	REGULATION OF IL–2 RECEPTOR BY THE CD4 LIGAND IL–16	118,800
K08MH001706–05	SCHEERINGA, MICHAEL S	TULANE UNIVERSITY OF LOUISIANA	TRAUMATIZED YOUNG CHILDREN-RISK FOR MALADAPTATION	149,858
K12HD043451–01	WHELTON, PAUL K	TULANE UNIVERSITY OF LOUISIANA	TULANE BIRCWH	435,408
K22ES011025–02	DUGAS, TAMMY R	LOUISIANA STATE UNIV HSC SHREVEPORT	COX–2 MEDIATED VASCULAR TOXICITY OF METHYLENEDIANILINE	108,000
K22HD001339–02	DONZE, DAVID	LOUISIANA STATE UNIV A&M COL BATON ROUGE	ANALYSIS OF CHROMOSOMAL INSULATOR/BOUNDARY ELEMENTS	134,200
K23RR016076–04	BERGGREN, RUTH E	TULANE UNIVERSITY OF LOUISIANA	MENTORED PATIENT ORIENTED RESEARCH CAREER DEVELOPMENT AW	123,390
K30HL004521–03	FRIEDMAN, MITCHELL	TULANE UNIVERSITY OF LOUISIANA	CLINICAL RESEARCH CURRICULUM AWARD	200,000
M01RR005096–13	WHELTON, PAUL K	TULANE UNIVERSITY OF LOUISIANA	GENERAL CLINICAL RESEARCH CENTER	2,588,372
P01DK043785–11A1	GRANGER, D NEIL	LOUISIANA STATE UNIV HSC SHREVEPORT	PATHOPHYSIOLOGY OF ISCHEMIA-REPERFUSION INJURY	1,486,250
P20RR016456–02	WISCHUSEN, EVERETT W	LOUISIANA STATE UNIV A&M COL BATON ROUGE	LOUISANA BIOMEDICAL RESEARCH NETWORK	1,807,933
P20RR016816–01	BAZAN, NICOLAS G	LOUISIANA STATE UNIV HSC NEW ORLEANS	MENTORING NEUROSCIENCE IN LOUISIANA	1,949,343
P20RR017659–01	NAVAR, L. GABRIEL	TULANE UNIVERSITY OF LOUISIANA	TULANE COBRE IN HYPERTENSION AND RENAL BIOLOGY	2,346,364
P30EY002377–24	KAUFMAN, HERBERT E	LOUISIANA STATE UNIV HSC NEW ORLEANS	CORE GRANT FOR VISION RESEARCH	519,951
P50AA009803–09	NELSON, STEVE	LOUISIANA STATE UNIV HSC NEW ORLEANS	ALCOHOL, HIV INFECTION AND HOST DEFENSE	1,645,309
P50AA009803–09S1	NELSON, STEVE	LOUISIANA STATE UNIV HSC NEW ORLEANS	ALCOHOL, HIV INFECTION AND HOST DEFENSE	126,708
P51RR000164–41	WHELTON, PAUL K	TULANE UNIVERSITY OF LOUISIANA	REGIONAL PRIMATE RESEARCH CENTER	7,879,003
R01AA009505–07	PRUETT, STEPHEN B	LOUISIANA STATE UNIV HSC SHREVEPORT	MECHANISMS OF IMMUNOSUPPRESSION BY ONE DOSE OF ETHANOL	181,208
R01AA009876–08	WOLCOTT, ROBERT M	LOUISIANA STATE UNIV HSC SHREVEPORT	FETAL ALCOHOL EFFECTS AND IMMUNE DEVELOPMENT	218,115
R01AA010384–07	KOLLS, JAY K.	LOUISIANA STATE UNIV HSC NEW ORLEANS	ALCOHOL, IMMUNOSUPPRESSION, AND TACE	286,000
R01AA012865–02	KASTIN, ABBA J	TULANE UNIVERSITY OF LOUISIANA	PEPTIDES AND ALCOHOL INTERACT AT THE BLOOD-BRAIN BARRIER	189,000
R01AA013543–01	MOLINA, PATRICIA E	LOUISIANA STATE UNIV HSC NEW ORLEANS	CHRONIC ALCOHOL & AIDS IMPACT ON MUSCLE WASTING	191,969
R01AA013563–01	VEAZEY, RONALD S	TULANE UNIVERSITY OF LOUISIANA	THE EFFECT ALCOHOL ON SIV PATHOGENESIS	283,392
R01AG016592–03	BERENSON, GERALD S	TULANE UNIVERSITY OF LOUISIANA	EVOLUTION OF CARDIOVASCULAR RISK WITH NORMAL AGING	697,574
R01AG017887–03	JAZWINSKI, S MICHAL	LOUISIANA STATE UNIV HSC NEW ORLEANS	NUTRITIONAL AND METABOLIC MECHANISMS OF AGING	286,000
R01AG017983–03	HAMMER, ROBERT P	LOUISIANA STATE UNIV A&M COL BATON ROUGE	INHIBITION OF FIBRILLOGENESIS WITH B–STRAND MIMICS	291,180
R01AG018031–02	LUKIW, WALTER J	LOUISIANA STATE UNIV HSC NEW ORLEANS	GENE EXPRESSION IN ALZHEIMER'S DISEASE	237,738
R01AG018239–03	GEISELMAN, PAULA J	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	OBESITY PREVENTION AFTER SMOKING CESSATION IN MENOPAUSE	183,416
R01AG018869–02	SUITOR, JILL J	LOUISIANA STATE UNIV A&M COL BATON ROUGE	PARENT-ADULT CHILD RELATIONS: WITHIN FAMILY DIFFERENCES	401,481
R01AI022001–18A1	O'CALLAGHAN, DENNIS J	LOUISIANA STATE UNIV HSC SHREVEPORT	NUCLEIC ACIDS OF HERPES VIRUS-INFECTED CELLS	468,495
R01AI022186–17	KLIMSTRA, WILLIAM B	LOUISIANA STATE UNIV HSC SHREVEPORT	MOLECULAR BASIS OF ALPHAVIRUS NEUROVIRULENCE	312,535
R01AI024030–15	ROBINSON, JAMES E	TULANE UNIVERSITY OF LOUISIANA	HIV–1 NEUTRALIZING HUMAN MABS	297,000
R01AI024912–15	CUTLER, JIM E	CHILDREN'S HOSPITAL (NEW ORLEANS)	CANDIDA ALBICANS SURFACE ANTIGENS	315,000
R01AI031567–08	CHERVENAK, ROBERT P	LOUISIANA STATE UNIV HSC SHREVEPORT	DEVELOPMENTAL BIOLOGY OF T CELL PRECURSORS	188,942
R01AI032556–08	FIDEL, PAUL L	LOUISIANA STATE UNIV HSC NEW ORLEANS	MUCOSAL CELL MEDIATED IMMUNITY IN VAGINAL CANDIDIASIS	203,775
R01AI039968–04A1	DIDIER, ELIZABETH SCHMIDT	TULANE UNIVERSITY OF LOUISIANA	MICROPORIDIOSIS IN AIDS	182,954
R01AI040667–07	VAN DER HEYDE, HENRI C	LOUISIANA STATE UNIV HSC SHREVEPORT	CELL ADHESION MOLECULES IN CEREBRAL MALARIA.	253,750
R01AI042146–04	MUGGERIDGE, MARTIN I	LOUISIANA STATE UNIV HSC SHREVEPORT	ROLES OF HSV2 MEMBRANE PROTEINS IN MEMBRANE FUSION	185,394
R01AI042400–03	DAVISON, BILLIE B	TULANE UNIVERSITY OF LOUISIANA	A RHESUS MONKEY MODEL OF MALARIA IN PREGNANCY	501,878

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
R01AI043000–04	KOUSOULAS, KONSTANTIN GUS	LOUISIANA STATE UNIV A&M COL BATON ROUGE	GENETICS & FUNCTIONS OF HSV1 GK IN VIRUS ENTRY & EGRESS	295,109
R01AI044596–05	MARX, PRESTON A	TULANE UNIVERSITY OF LOUISIANA	SIV–RCM AND RELATED PRIMATE LENTIVIRUSES IN WEST AFRICA	542,776
R01AI045041–04	HURLBURT, BARRY K	U.S. AGRICULTURE RESEARCH SERVICE–MIDSOU	MECHANISMS OF VIRULENCE GENE REGULATION IN S. AUREUS	272,803
R01AI045151–03	FREYTAG, LUCIA C	TULANE UNIVERSITY OF LOUISIANA	MUCOSAL IMMUNIZATION—PREVENTION OF SYSTEMIC CANDIDIASIS	222,750
R01AI045725–03	GILLIS, THOMAS P	NATIONAL HANSEN'S DISEASE PROGRAM	DEVELOP AND EVALUATE NEW LEPROSY AND TB VACCINES	116,990
R01AI046275–04	ROBINSON, JAMES E	TULANE UNIVERSITY OF LOUISIANA	RHESUS MABS FROM SHIV INFECTED MACAQUES	234,049
R01AI047693–03	BUNNELL, BRUCE A	TULANE UNIVERSITY OF LOUISIANA	INTRAMARROW GENE TRANSFER IN NEONATES	327,456
R01AI049080–01A1S1	VEAZEY, RONALD S	TULANE UNIVERSITY OF LOUISIANA	MECHANISMS OF CD4 DEPLETION AND PROLIFERATION IN SIV	11,499
R01AI049080–02	VEAZEY, RONALD S	TULANE UNIVERSITY OF LOUISIANA	MECHANISMS OF CD4 DEPLETION AND PROLIFERATION IN SIV	442,426
R01AI049139–02	OBERHELMAN, RICHARD A	TULANE UNIVERSITY OF LOUISIANA	PRACTICAL DIAGNOSTICS FOR AIDS-RELATED PEDIATRIC TB, PERU	206,190
R01AI049193–01A1	PETERSON, KENNETH M	LOUISIANA STATE UNIV HSC SHREVEPORT	SIGNAL TRANS. AND INTESTINAL COLONIZATION BY V. CHOLERAE	278,750
R01AI049293–01A2	RAMAMOORTHY, RAMESH	TULANE UNIVERSITY OF LOUISIANA	RPOS AND GENE EXPRESSION IN BORRELIA BURGDORFERI	200,000
R01AI049744–01A2	BEILKE, MARK A	TULANE UNIVERSITY OF LOUISIANA	RETROVIRAL CO-INFECTIONS: HIV, HTLV AND DRUG ABUSE	359,125
R01AI049976–01S1	PHILIPP, MARIO T	TULANE UNIVERSITY OF LOUISIANA	'LYME DISEASE: A POSSIBLE TEST FOR CURE	24,000
R01AI049976–02	PHILIPP, MARIO T	TULANE UNIVERSITY OF LOUISIANA	'LYME DISEASE: A POSSIBLE TEST FOR CURE	160,000
R01AI050027–01A1	ADAMS, LINDA B	NATIONAL HANSEN'S DISEASE PROGRAM	GENE KNOCK–OUT MICE AS MODELS FOR THE LEPROSY SPECTRUM	150,000
R01AI051677–01	SHELLITO, JUDD E	LOUISIANA STATE UNIV HSC NEW ORLEANS	IL–17 AND KLEBSIELLA PNEUMONIA	315,026
R01AR045982–05	ALA–KOKKA, LEENA M	TULANE UNIVERSITY OF LOUISIANA	MUTATIONS CAUSING DISC DISEASE AND SCIATICA	288,509
R01AR046976–04	KIMPEL, DONALD L	LOUISIANA STATE UNIV HSC SHREVEPORT	NOVEL IMAGING TECHNOLOGIES FOR RHEUMATOID ARTHRITIS	290,000
R01AR048323–02	PROCKOP, DARWIN J	TULANE UNIVERSITY OF LOUISIANA	OSTEOPROGENITORS FOR POTENTIAL THERAPY OF OI	371,250
R01CA054152–10A2	HILL, STEVEN M	TULANE UNIVERSITY OF LOUISIANA	NEUROENDOCRINE INFLUENCES ON MAMMARY CANCER	291,199
R01CA067372–08	SIXBEY, JOHN W.	LOUISIANA STATE UNIV HSC SHREVEPORT	EPSTEIN BARR VIRUS INDUCED GENOMIC INSTABILITY	326,250
R01CA074731–04A2	LEVY, LAURA S.	TULANE UNIVERSITY OF LOUISIANA	PATHOBIOLOGY OF SAIDS–ASSOCIATED LYMPHOMAS	257,753
R01CA078335–04	GNARRA, JAMES R	LOUISIANA STATE UNIV HSC NEW ORLEANS	HGF/SF SIGNALING BY THE VHL TUMOR SUPPRESSOR	295,132
R01CA080149–04	MATHIS, J MICHAEL	LOUISIANA STATE UNIV HSC SHREVEPORT	ADENOVIRUS BASED P53 GENE THERAPY FOR OVARIAN CANCER	114,527
R01CA081125–04	SCHWARZENBERGER, PAUL O	LOUISIANA STATE UNIV HSC NEW ORLEANS	IL–17 AND HEMATOPOIESIS	177,500
R01CA081506–03	EHRLICH, MELANIE	TULANE UNIVERSITY OF LOUISIANA	DNA HYPOMETHYLATION AND CANCER	259,058
R01CA082689–04	OCHOA, AUGUSTO C.	LOUISIANA STATE UNIV HSC NEW ORLEANS	ARGININE REGULATES T CELL SIGNAL TRANSDUCTION & FUNCTION	248,500
R01CA083823–03	LEVY, LAURA S.	TULANE UNIVERSITY OF LOUISIANA	SELECTIVE FORCES OPERATIVE IN FELV INFECTION	246,155
R01CA085693–03	HARRISON, LYNN	LOUISIANA STATE UNIV HSC SHREVEPORT	DNA REPAIR OF MULTIPLY DAMAGED SITES IN CELLS	195,750
R01CA088885–02	OCHOA, AUGUSTO C.	LOUISIANA STATE UNIV HSC NEW ORLEANS	IMMUNE DYSFUNCTION AND IMMUNOTHERAPY OF RENAL CANCER	225,602
R01CA089057–02	LI, LI	OCHSNER CLINIC FOUNDATION	STROMAL CELL MOLECULES REQUIRED FOR LYMPHOMA GENERATION	166,250
R01CA089121–02	DASH, SRIKANTA A.	TULANE UNIVERSITY OF LOUISIANA	HEPATITIS C VIRUS AND HEPATOCELLULAR CARCINOMA	233,888
R01CA092126–01A1	CHOI, YONG S	OCHSNER CLINIC FOUNDATION	LYMPHOMAGENESIS	221,113
R01CA095783–02	JONES, FRANK E	TULANE UNIVERSITY OF LOUISIANA	ERBB4 SIGNALING IN THE NORMAL AND NEOPLASTIC BREAST	217,390
R01DA005084–15	LINDBERG, IRIS	LOUISIANA STATE UNIV HSC NEW ORLEANS	OPIOID PEPTIDE SYNTHESIZING ENZYMES	181,401
R01DA011417–04	MOERSCHBAECHER, JOSEPH M.	LOUISIANA STATE UNIV HSC NEW ORLEANS	CANNABINOID ABUSE EFFECTS ON LEARNING AND MEMORY	200,650
R01DA011939–03	HARLAN, RICHARD E	TULANE UNIVERSITY OF LOUISIANA	THALAMOSTRIATAL MECHANISMS OF MORPHINE ACTION	179,465

R01DA012267–03S2	HARRISON, MURELLE G	SOUTHERN UNIV A&M COL BATON ROUGE	PREVENTING SUBSTANCE USE IN RURAL AFRICAN-AMERICAN YOUTH	38,856
R01DA012267–04	HARRISON, MURELLE G	SOUTHERN UNIV A&M COL BATON ROUGE	PREVENTING SUBSTANCE USE IN RURAL AFRICAN-AMERICAN YOUTH	382,294
R01DA012267–04S1	HARRISON, MURELLE G	SOUTHERN UNIV A&M COL BATON ROUGE	PREVENTING SUBSTANCE USE IN RURAL AFRICAN-AMERICAN YOUTH	112,134
R01DA012427–03	WINSAUER, PETER J	LOUISIANA STATE UNIV HSC NEW ORLEANS	COCAINE SELF-ADMINSTRATION: EFFECTS ON LEARNING	100,570
R01DA012703–04	TRUDELL, MARK L	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	NOVEL NICOTINIC RECEPTOR MEDIATED THERAPEUTIC AGENTS	311,219
R01DA013463–02	GOEDERS, NICHOLAS E	LOUISIANA STATE UNIV HSC SHREVEPORT	ROLE FOR THE HPA AXIS IN METHAMPHETAMINE REINFORCEMENT	320,554
R01DA013899–02	MORSE, EDWARD V	TULANE UNIVERSITY OF LOUISIANA	RISK REDUCTION FOR YOUNG AFRICAN AMERICAN IDUS	566,386
R01DC003679–04	HOOD, LINDA JEAN	LOUISIANA STATE UNIV HSC NEW ORLEANS	AUDITORY GENETIC STUDIES OF HEREDITARY HEARING LOSS	213,503
R01DC003792–04	CAPRIO, JOHN T	LOUISIANA STATE UNIV A&M COL BATON ROUGE	ENCODING OF BIOLOGICALLY RELEVANT ODOR SIGNALS	329,574
R01DC003896–04	RICCI, ANTHONY J	LOUISIANA STATE UNIV HSC NEW ORLEANS	ENDOGENOUS FACTORS REGULATING TRANSDUCER ADAPTATION	170,977
R01DC003896–04S1	RICCI, ANTHONY J	LOUISIANA STATE UNIV HSC NEW ORLEANS	ENDOGENOUS FACTORS REGULATING TRANSDUCER ADAPTATION	54,450
R01DC004196–04	KEATS, BRONYA J.	LOUISIANA STATE UNIV HSC NEW ORLEANS	ID OF THE MOUSE DEAFNESS (DN) GENE ON CHROMOSOME 19	230,769
R01DE008911–11	WISE, GARY E	LOUISIANA STATE UNIV A&M COL BATON ROUGE	MOLECULAR BASIS OF TOOTH ERUPTION	178,924
R01DE012329–04	CHEN, YIPING	TULANE UNIVERSITY OF LOUISIANA	MOLECULAR MECHANISMS OF VERTEBRATE TOOTH INITIATION	185,282
R01DE012916–04	AMEDEE, ANGELA M	LOUISIANA STATE UNIV HSC NEW ORLEANS	SIV MACAQUE MODEL FOR BREAST MILK TRANSMISSION OF HIV	257,756
R01DE014044–01A1	CHEN, YIPING	TULANE UNIVERSITY OF LOUISIANA	GROWTH FACTOR SIGNALING IN MOUSE PALATOGENESIS	297,000
R01DK041279–10	GLASS, JONATHAN D	LOUISIANA STATE UNIV HSC SHREVEPORT	MOLECULAR MECHANISMS OF INTESTINAL IRON TRANSPORT	246,500
R01DK041868–11S1	HWANG, DANIEL H	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	DIETARY N 3 FATTY ACIDS AND EXPRESSION OF CYCLOOXYGENASE	85,260
R01DK044510–09	AW, TAK Y	LOUISIANA STATE UNIV HSC SHREVEPORT	GLUTATHIONE REDOX CONTROL OF INTESTINAL CELL RESPONSES	261,000
R01DK045278–10	YORK, DAVID A.	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	ENTEROSTATIN REGULATION OF FAT INTAKE	330,750
R01DK046935–08	LANCASTER, JACK R.	LOUISIANA STATE UNIV HSC NEW ORLEANS	NITROGEN AND OXYGEN RADICAL INTERACTIONS IN SURGERY	204,820
R01DK047211–08	VEDECKIS, WAYNE V.	LOUISIANA STATE UNIV HSC NEW ORLEANS	REGULATION OF GLUCOCORTICOID RECEPTOR GENE EXPRESSION	186,014
R01DK047348–09	BERTHOUD, HANS-RUDOLF	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	AUTONOMIC REGULATION OF FOOD INTAKE AND METABOLISM	185,241
R01DK047663–08	GRISHAM, MATTHEW B	LOUISIANA STATE UNIV HSC SHREVEPORT	ADHESION MOLECULE EXPRESSION IN CHRONIC GUT INFLAMMATION	182,736
R01DK048055–07	MCCARTHY, KEVIN J.	LOUISIANA STATE UNIV HSC SHREVEPORT	PROTEOGLYCANS IN DIABETIC NEPHROPATHY	290,000
R01DK049703–06A1	LINDBERG, IRIS	LOUISIANA STATE UNIV HSC NEW ORLEANS	CONTROL OF PEPTIDE HORMONE BIOSYNTHESIS BY PC2 AND 7B2	310,483
R01DK050550–09	LACKNER, ANDREW A	TULANE UNIVERSITY OF LOUISIANA	MECHANISMS OF INTESTINAL DYSFUNCTION IN SIMIAN AIDS	468,334
R01DK050736–04S1	LOVEJOY, JENNIFER C	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	MENOPAUSE EFFECT ON OBESITY, ENERGY BALANCE AND INSULIN	167,018
R01DK052142–05A1	ROGERS, RICHARD C	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	TNF, VAGAL TONE AND GASTRIC MOTILITY	328,897
R01DK052968–04	STEPHENS, JACQUELINE M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	REGULATION AND ACTIVATION OF STATS IN ADIPOCYTES	189,070
R01DK053872–05	CLARKE, STEVEN D	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	CONTROL OF GENE TRANSCRIPTION BY ESSENTIAL FATTY ACIDS	159,475
R01DK054880–04	KASTIN, ABBA J	TULANE UNIVERSITY OF LOUISIANA	BLOOD/BRAIN BARRIER AND LEPTIN TRANSPORT IN OBESITY	328,290
R01DK054952–03	HAMM, L. LEE	TULANE UNIVERSITY OF LOUISIANA	REGULATION OF CITRATE TRANSPORT	198,450
R01DK055626–03	AWAYDA, MOUHAMED S.	TULANE UNIVERSITY OF LOUISIANA	KINASE REGULATION OF THE EPITHELIAL NA CHANNEL	222,750
R01DK056132–02	SMITH, BRET N	TULANE UNIVERSITY OF LOUISIANA	NEURAL CIRCUITRY IN THE CAUDAL SOLITARY COMPLEX	222,750
R01DK056264–03	EL-DAHR, SAMIR S.	TULANE UNIVERSITY OF LOUISIANA	INDUCIBLE DYSPLASTIC NEPHROPATHY IN B2-DEFICENT MICE	267,300
R01DK056373–05	ROGERS, RICHARD G	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	BRAINSTEM ESOPHAGEAL—GASTRIC CONTROL REFLEXES	138,630
R01DK057242–03	BERTHOUD, HANS–RUDOLF	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	FUNCTIONAL ORGANIZATION OF THE VAGAL-ENTERIC INTERFACE	191,739
R01DK058152–03	KOZAK, LESLIE P	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	GENETICS OF DEVELOPMENTAL PLASTICITY IN THE ADIPOCYTE	445,163
R01DK058499–02	AGRAWAL, KRISHNA C	TULANE UNIVERSITY OF LOUISIANA	PROTEASE INHIBITOR RELATED ADIPOGENESIS IN HIV INFECTION	282,150

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
R01DK059326–01A1	BRISKI, KAREN P	UNIVERSITY OF LOUISIANA AT MONROE	CAUDAL BRAIN STEM LACTATE AVAILABILITY REGULATES FEEDING	81,699
R01DK060412–02	RAVUSSIN, ERIC	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	FAT CELL SIZE, MUSCLE LIPID INFILTRATION AND INSULIN RE*	560,060
R01DK062003–01	HARRISON–BERNARD, LISA M	TULANE UNIVERSITY OF LOUISIANA	AT1 RECEPTORS IN RENAL MICROVASCULAR PHYSIOLOGY	283,635
R01DK063453–01	WILLIAMSON, DONALD A.	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	WISE MIND: ENVIRONMENTAL APPROACH FOR OBESITY PREVENTION	220,500
R01DK063669–01	ORLANDO, ROY C	TULANE UNIVERSITY OF LOUISIANA	MECHANISMS OF ACID RESISTANCE IN BARRETT'S ESOPHAGUS	311,100
R01DK064156–01	CLARKE, STEVEN D	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	DELTA–6 AND DELTA–5 DESATURASES	280,770
R01EB000242–03	KHOOBEHI, BAHRAM	LOUISIANA STATE UNIV HSC NEW ORLEANS	RETINAL AND CHOROIDAL BLOOD FLOW IMAGING	207,586
R01EB000739–01	MCSHANE, MICHAEL J	LOUISIANA TECHNOLOGICAL UNIVERSITY	FLUORESCENT GLUCOSE SENSORS FROM POLYION MICROSHELLS	292,116
R01ES004344–11A1	BACKES, WAYNE L	LOUISIANA STATE UNIV HSC NEW ORLEANS	TOXICOLOGICAL SIGNIFICANCE OF ALKYLBENZENE METABOLISM	315,300
R01ES006766–09	BRODY, ARNOLD R	TULANE UNIVERSITY OF LOUISIANA	GROWTH FACTORS IN ASBESTOS INDUCED PULMONARY FIBROSIS	255,518
R01ES009158–06	PRUETT, STEPHEN B	LOUISIANA STATE UNIV HSC SHREVEPORT	MECHANISMS OF IMMUNOTOXCITY OF CHEMICAL STRESSORS	207,375
R01ES009870–03	MEHENDALE, HARIHARA M	UNIVERSITY OF LOUISIANA AT MONROE	DIETARY RESTRICTION AND TOXICANT-INDUCED LIVER DISEASE	188,055
R01ES010046–03	LASKY, JOSEPH A	TULANE UNIVERSITY OF LOUISIANA	DISRUPTION OF PDGF SIGNAL TRANSDUCTION IN LUNG FIBROSIS	259,875
R01ES010497–03	MURRAY, KERMIT K	LOUISIANA STATE UNIV A&M COL BATON ROUGE	REAL TIME MASS SPECTROMETRY OF BIOAEROSOLS	147,000
R01ES010859–01A1	ORTIZ, LUIS A.	TULANE UNIVERSITY OF LOUISIANA	TNF–ALPHA SIGNALING IN SILICA-INDUCED LUNG FIBROSIS	289,725
R01EY002672–24	KAUFMAN, HERBERT E	LOUISIANA STATE UNIV HSC NEW ORLEANS	OCULAR HERPES SIMPLEX VIRUS	336,000
R01EY003311–23	KLYCE, STEPHEN D	LOUISIANA STATE UNIV HSC NEW ORLEANS	INTEGRATED ASSESSMENT OF CORNEAL FORM AND FUNCTION	315,720
R01EY004928–20	BAZAN, HAYDEE E	LOUISIANA STATE UNIV HSC NEW ORLEANS	CORNEAL LIPID METABOLISM AND RESPONSE TO INFLAMMATION	203,086
R01EY005121–18	BAZAN, NICOLAS G	LOUISIANA STATE UNIV HSC NEW ORLEANS	RPE MESSENGERS, TRANSCRIPTION AND PHOTORECEPTOR RENEWAL	250,250
R01EY006311–17	HILL, JAMES M	LOUISIANA STATE UNIV HSC NEW ORLEANS	OCULAR HSV-LATENCY, REACTIVATION, AND RECURRENCE	387,224
R01EY007380–13	MENERAY, MICHELE A	LOUISIANA STATE UNIV HSC NEW ORLEANS	INTERACTIVE CELLULAR CONTROLS LACRIMAL GLAND FUNCTIONAL	286,000
R01EY011610–05	BURGOYNE, CLAUDE F	LOUISIANA STATE UNIV HSC NEW ORLEANS	IOP–RELATED FORCE AND FAILURE IN THE OPTIC NERVE HEAD	616,605
R01EY012416–04	BEUERMAN, ROGER W	LOUISIANA STATE UNIV HSC NEW ORLEANS	REGULATION OF PROTEIN SYNTHESIS IN THE LACRIMAL GLAND	224,832
R01EY012540–04	PALKAMA, ARTO K	LOUISIANA STATE UNIV HSC NEW ORLEANS	AQUEOUS OUTFLOW AND STRUCTURAL CORRELATIONS	300,113
R01EY012701–03	CHANDRASEKHER, GUDISEVA	LOUISIANA STATE UNIV HSC NEW ORLEANS	GROWTH FACTOR RECEPTOR MEDITATED SIGNAL MECHANISMS LENS	176,170
R01EY012716–02	GUIDO, WILLIAM	LOUISIANA STATE UNIV HSC NEW ORLEANS	FUNCTIONAL STATE OF DEVELOPING RETINOGENICULATE SYNAPSE	178,750
R01EY012961–03	O'CALLAGHAN, RICHARD J	LOUISIANA STATE UNIV HSC NEW ORLEANS	MECHANISMS AND THERAPY OF BACTERIAL KERATITIS	286,000
R01EY013176–01A2	ALLIEGRO, MARK C.	LOUISIANA STATE UNIV HSC NEW ORLEANS	NOVEL GENES EXPRESSED IN PROLIFERATING ENDOTHELIAL CELLS	204,690
R01EY013325–01A1	KWON, BYOUNG S	LOUISIANA STATE UNIV HSC NEW ORLEANS	OCULAR HSV–1, STROMAL KERATITIS, & T CELL COSTIMULATION	315,415
R01GM020818–28A1	RHOADS, ROBERT E.	LOUISIANA STATE UNIV HSC SHREVEPORT	REGULATION OF EUKARYOTIC PROTEIN SYNTHESIS INITIATION	320,850
R01GM039844–12	WARNER, ISIAH M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	BIOANALYTICAL SEPARATION USING CHIRAL POLYMERS	273,533
R01GM045668–10A1	DEININGER, PRESCOTT L	TULANE UNIVERSITY OF LOUISIANA	SINE RETROTRANSPOSITION	259,875
R01GM047789–18	TATCHELL, KELLY G.	LOUISIANA STATE UNIV HSC SHREVEPORT	GENETIC ANALYSIS OF PROTEIN PHOSPHATASE 1 IN YEAST	228,375
R01GM051521–09	WITT, STEPHEN N.	LOUISIANA STATE UNIV HSC SHREVEPORT	KINETICS AND MECHANISM OF THE HEAT SHOCK 70 PROTEIN DNAK	205,446
R01GM055420–12	NEWCOMER, MARCIA E.	LOUISIANA STATE UNIV A&M COL BATON ROUGE	ENZYMATIC ACTIVATION OF LIPOPHILIC SIGNALING MOLECULES	235,200
R01GM059663–02	WITTUNG–STAFSHEDE, PERNILLA E	TULANE UNIVERSITY OF LOUISIANA	COFACTOR ROLE IN BETA–SHEET PROTEIN FOLDING	175,770
R01GM060000–02	WIMLEY, WILLIAM C	TULANE UNIVERSITY OF LOUISIANA	FOLDING AND DESIGN OF BETA SHEETS IN MEMBRANES	185,625
R01GM061915–02	STRONGIN, ROBERT M	LOUISIANA STATE UNIV A&M COL BATON ROUGE	SYNTHESIS AND STUDY OF NOVEL SENSING AGENTS	183,750

R01HD008431–27	KOZAK, LESLIE P	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	MOLECULAR GENETICS OF THERMOGENESIS	321,299
R01HD036822–04	WANG, YU–PING	LOUISIANA STATE UNIV HSC SHREVEPORT	PLACENTAL FUNCTION IN PREECLAMPSIA	145,425
R01HD037811–03	GASSER, RAYMOND F	LOUISIANA STATE UNIV HSC NEW ORLEANS	HUMAN EMBRYO SECTIONS ON DVDS FOR EDUCATION	326,032
R01HD039104–03	WILLIAMSON, DONALD A.	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	INTERNET–BASED OBESITY PREVENTION FOR BLACK ADOLESCENTS	160,073
R01HG001499–06	SOPER, STEVEN A	LOUISIANA STATE UNIV A&M COL BATON ROUGE	HIGH THROUGHPUT DNA SEQUENCING USING NANO–REACTORS	428,179
R01HL018426–28	NAVAR, L. GABRIEL	TULANE UNIVERSITY OF LOUISIANA	REGULATION OF RENAL HEMODYNAMICS	334,125
R01HL022252–26	ROSELLI, CHARLES E.	LOUISIANA STATE UNIV A&M COL BATON ROUGE	SYNTHESES OF HEMES FOR PROTEIN STUDIES	367,500
R01HL026371–21	NAVAR, L. GABRIEL	TULANE UNIVERSITY OF LOUISIANA	RENAL FUNCTIONAL DERANGEMENTS IN HYPERTENSION	336,341
R01HL026441–22	GRANGER, D NEIL	LOUISIANA STATE UNIV HSC SHREVEPORT	TRANSCAPILLARY FLUID EXCHANGE	255,138
R01HL032788–16	CHILIAN, WILLIAM M	LOUISIANA STATE UNIV HSC NEW ORLEANS	MICROCIRCULATORY DYNAMICS IN THE CORONARY CIRCULATION	320,215
R01HL045670–11	BOUCHARD, CLAUDE	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	HERITAGE–GENETICS, RESPONSE TO EXERCISE, RISK FACTORS–3	749,187
R01HL054797–09	KORTHUIS, RONALD J	LOUISIANA STATE UNIV HSC SHREVEPORT	PRECONDITIONING: PMN ADHESION AND MICROVASCULAR INJURY	290,000
R01HL057531–05A1	PANDEY, KAILASH N	TULANE UNIVERSITY OF LOUISIANA	ANP Receptor: Molecular approach of signaling mechanisms	222,750
R01HL060532–06	Brody, Arnold R	TULANE UNIVERSITY OF LOUISIANA	TGF–B in Interstitial Lung Disease	334,125
R01HL060849–04	LEFER, DAVID J	LOUISIANA STATE UNIV HSC SHREVEPORT	MECHANISMS OF MYOCARDIAL REPERFUSION INJURY--DIABETES	184,285
R01HL061271–04	Kolls, Jay K.	LOUISIANA STATE UNIV HSC NEW ORLEANS	NON CD4 HOST DEFENSE AGAINST P CARINII PNEUMONIA	78,314
R01HL061934–06	MORRIS, CINDY A	TULANE UNIVERSITY OF LOUISIANA	MOLECULAR MECHANISM OF TAT INDUCED ANGIOGENESIS	222,750
R01HL062000–03	HYMAN, ALBERT L	TULANE UNIVERSITY OF LOUISIANA	CARDIOPULMONARY SURGERY RESEARCH	302,940
R01HL062052–05	Kolls, Jay K.	LOUISIANA STATE UNIV HSC NEW ORLEANS	CD8 AND GAMMA/DELTA T CELLS IN P CARINII PNEUMONIA	255,226
R01HL063128–03	AGRAWAL, KRISHNA C	TULANE UNIVERSITY OF LOUISIANA	MECHANISMS OF CARDIOVASCULAR COMPLICATIONS IN AIDS	299,899
R01HL063195–04	TRAYANOVA, NATALIA A	TULANE UNIVERSITY OF LOUISIANA	CARDIAC TISSUE STRUCTURE IN THE DEFIBRILLATION PROCESS	171,030
R01HL063778–02	LASKY, JOSEPH A	TULANE UNIVERSITY OF LOUISIANA	CTGF IN LUNG FIBROGENESIS	259,875
R01HL064577–04	JOHNSON, ROBERT A	TULANE UNIVERSITY OF LOUISIANA	HEMODYNAMIC ROLES OF ENDOGENEOUS CARBON MONOXIDE	166,634
R01HL065997–02	WANG, YU–PING	LOUISIANA STATE UNIV HSC SHREVEPORT	ENDOTHELIAL BARRIER FUNCTION IN PREECLAMPSIA	217,500
R01HL066158–02	VEHASKARI, V M	LOUISIANA STATE UNIV HSC NEW ORLEANS	Prenatal and Perinatal Programming of Adult Hypertension	214,500
R01HL066432–02	MAJID, DEWAN S	TULANE UNIVERSITY OF LOUISIANA	Superoxide and nitric Oxide Interactions in the Kidney	222,750
R01HL068057–01A1	HE, JIANG	TULANE UNIVERSITY OF LOUISIANA	Clinical Trial of Dietary Protein on Blood Pressure	655,198
R01HL069029–01	FEELISCH, MARTIN	LOUISIANA STATE UNIV HSC SHREVEPORT	Redox-activation of vascular stores of NO by vitamin C	340,000
R01HL073774–01	FARLEY, THOMAS A	TULANE UNIVERSITY OF LOUISIANA	ATTENDED CITY SCHOOLYARDS TO INCREASE PHYSICAL ACTIVITY	222,750
R01LM007591–01	CORK, ROBERT J	LOUISIANA STATE UNIV HSC NEW ORLEANS	Enhancements to a human embryo, serial-section database	101,460
R01MH059931–03	LANIER, STEPHEN M	LOUISIANA STATE UNIV HSC NEW ORLEANS	A TRANSDUCTION COMPLEX FOR G PROTEIN COUPLED RECEPTORS	240,693
R01MH061192–05	LACKNER, ANDREW A	TULANE UNIVERSITY OF LOUISIANA	CHEMOKINE RECEPTORS IN THE NEUROPATHOGENESIS OF AIDS	284,869
R01MH062640–01A2	LEIDENHEIMER, NANCY J	LOUISIANA STATE UNIV HSC SHREVEPORT	Regulation of GABAA Receptor Cell Surface Expression	264,961
R01NS009626–32	LI, YU–TEH	TULANE UNIVERSITY OF LOUISIANA	GLYCOSIDASES AS RELATED TO SPHINGOLIPIDOSES	382,466
R01NS023002–16A1	BAZAN, NICOLAS G	LOUISIANA STATE UNIV HSC NEW ORLEANS	Phospholipid and Arachidonic Acid Signaling in Epilepsy	270,275
R01NS024821–13	LANIER, STEPHEN M	LOUISIANA STATE UNIV HSC NEW ORLEANS	STRUCTURAL ANALYSIS OF THE ALPHA 2 ADRENERGIC RECEPTOR	213,269
R01NS025987–15	PHELPS, CAROL J.	TULANE UNIVERSITY OF LOUISIANA	HYPOPHYSIOTROPIC NEURON DIFFERENTIATION--TARGET FEEDBACK	219,774
R01NS030769–11	LACKNER, ANDREW A	TULANE UNIVERSITY OF LOUISIANA	NEUROPATHOGENESIS OF PEDIATRIC AIDS: A SIV MODEL	345,144
R01NS035370–10	DUNN, ADRIAN J	LOUISIANA STATE UNIV HSC SHREVEPORT	Cytokine Action on the CNS	253,750
R01NS037963–04A1	CANAVIER, CARMEN C	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	Firing Pattern in Midbrain Dopamine Neurons	168,625

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
R01NS039033–02	PHINNEY, DONALD G	TULANE UNIVERSITY OF LOUISIANA	Marrow stromal cells for Lysosomal Disease CNS Defects	259,875
R01NS039033–02S1	PHINNEY, DONALD G	TULANE UNIVERSITY OF LOUISIANA	Marrow stromal cells for Lysosomal Disease CNS Defects	72,765
R01NS039050–03	ERZURUMLU, REHA S	LOUISIANA STATE UNIV HSC NEW ORLEANS	SOMATOSENSORY CORTICAL DEVELOPMENT AND PLASTICITY	143,000
R01NS039099–03	TASKER, JEFFREY G	TULANE UNIVERSITY OF LOUISIANA	HYPOTHALAMIC SYNCHRONIZATION BY LOCAL GLUTAMATE CIRCUITS	259,875
R01NS039458–03	MAGEE, JEFFERY C	LOUISIANA STATE UNIV HSC NEW ORLEANS	DENDRITIC INTEGRATION IN HIPPOCAMPAL PYRAMIDAL NEURONS	230,823
R01NS039458–03S1	MAGEE, JEFFERY C	LOUISIANA STATE UNIV HSC NEW ORLEANS	DENDRITIC INTEGRATION IN HIPPOCAMPAL PYRAMIDAL NEURONS	50,000
R01NS040373–02	ARIMURA, AKIRA A	TULANE UNIVERSITY OF LOUISIANA	Neuroprotection by PACAP in Stroke	371,250
R01NS044000–02	BASTIAN, FRANK O	TULANE UNIVERSITY OF LOUISIANA	Spiroplasma 16S rDNA in TSE Brain Tissues	185,625
R01NS045694–01	ZHANG, JOHN H	LOUISIANA STATE UNIV HSC SHREVEPORT	Anti-apoptosis as a new therapy for cerebral vasospasm	253,750
R01NS045954–01	TAYLOR, BRADLEY K	TULANE UNIVERSITY OF LOUISIANA	NEUROPEPTIDERGIC INHIBITION OF SPINAL PAIN TRANSMISSION	352,688
R03CA083096–02	Johnson, Eric S.	TULANE UNIVERSITY OF LOUISIANA	POSSIBLE OF ROLE OF AVIAN RETROVIRUSES IN HUMAN CANCER	74,250
R03CA091185–01A1	RAJ, MADHWA H	LOUISIANA STATE UNIV HSC NEW ORLEANS	A new tumor marker for Ovarian Cancer	71,208
R03CA097778–01	MANDAL, DIPTASRI M	LOUISIANA STATE UNIV HSC NEW ORLEANS	Genetics of Prostate Cancer in an Af-Am Population	35,500
R03DA013647–02	GOEDERS, NICHOLAS E	LOUISIANA STATE UNIV HSC SHREVEPORT	Neurochemistry of Cocaine Reinforcement	72,500
R03DA015618–01	PHADTARE, SHASHIKANT K	XAVIER UNIVERSITY OF LOUISIANA	NEW PHENYL NUCLEOSIDES AS ANTI-HIV AGENTS	72,554
R03DC004957–01A2	FOUNDAS, ANNE L	TULANE UNIVERSITY OF LOUISIANA	Developmental Stuttering: MRI Studies in Children	74,250
R03EY014021–01	JACOB, JEAN T	LOUISIANA STATE UNIV HSC NEW ORLEANS	Capillary Electrophoresis Profiling of Tears in Dry Eye	135,619
R03EY014135–01	NAUMAN, ERIC A	TULANE UNIVERSITY OF LOUISIANA	Intraocular Pressure-Mediated Damage to the Optic Nerve	141,225
R03HD041052–02	SCHMIDT–SOMMERFELD, EBERHARD	LOUISIANA STATE UNIV HSC NEW ORLEANS	Parenteral Medium Chain Triglycerides in the Premature	71,500
R03HD042003–01	VANLANDINGHAM, MARK J	TULANE UNIVERSITY OF LOUISIANA	Migration Effects on Health of Working Age Vietnamese	74,250
R03MH065943–01	STAFFORD, BRIAN S	TULANE UNIVERSITY OF LOUISIANA	Validity of Reactive Attachment Disorder	74,250
R13AA013578–01	MOLINA, PATRICIA E	LOUISIANA STATE UNIV HSC NEW ORLEANS	Alcoholism and Disease: Immune/Pathological Mechanisms	38,100
R13AG021441–01	GRISHAM, MATTHEW B	LOUISIANA STATE UNIV HSC SHREVEPORT	Ninth Annual Oxygen Society Meeting	15,000
R13DA015297–01	Harlan, Richard E	TULANE UNIVERSITY OF LOUISIANA	Workshop on Steroid Hormones and Brain Function	15,650
R13HL069204–01	GRISHAM, MATTHEW B	LOUISIANA STATE UNIV HSC SHREVEPORT	Eighth Annual Oxygen Society Meeting	20,000
R15DA013512–01A2	MANDAL, TARUN K	XAVIER UNIVERSITY OF LOUISIANA	SR Drug Delivery for the Treatment of Drug Abuse	68,113
R15ES011279–01A1	ASRABADI, BADIOLLAH R	NICHOLLS STATE UNIVERSITY	Air Pollution and Asthma in Southeast Louisiana	151,000
R18AI033449–08	FREY, DANIEL J	LOUISIANA ORGAN PROCUREMENT AGENCY	ENHANCING DONOR REGISTRY TO INCREASE DONATION	387,407
R21AA013555–01A1	McDonough, Kathleen H	LOUISIANA STATE UNIV HSC NEW ORLEANS	Alcohol Enhances HIV–1 Induced Cardiac Depression	139,903
R21AA013828–01	MACLEAN, ANDREW G	TULANE UNIVERSITY OF LOUISIANA	Alcohol and SIV neuroinvasion in vivo and in vitro	160,000
R21AI051414–01	HALFORD, WILLIAM P	TULANE UNIVERSITY OF LOUISIANA	ROLE OF THE LAT–ICP0 LOCUS IN REGULATING HSV LATENCY	284,875
R21AI053290–01	RAMSAY, ALISTAIR J	LOUISIANA STATE UNIV HSC NEW ORLEANS	Generation of protection against 'stealth' poxviruses	210,900
R21AI053517–01	LINDBERG, IRIS	LOUISIANA STATE UNIV HSC NEW ORLEANS	Blockade of Anthrax Cytotoxicity Using Furin Inhibitors	204,600
R21CA089348–01A2	SINGAL, RAKESH	U.S. DEPT/VETS AFFAIRS MED CTR(SHREVPRT)	GSTP1 gene repression in prostate cancer	75,000
R21DA016029–01	MOHAMADZADEH, MANSOUR	TULANE UNIVERSITY OF LOUISIANA	Dendritic cell targeted hepatitis c virus immunotherapy	148,500
R21DC004994–02	BOBBIN, RICHARD P	LOUISIANA STATE UNIV HSC NEW ORLEANS	Drug manipulation of noise-induced hearing loss	143,000
R21DC005470–01	Ricci, Anthony J	LOUISIANA STATE UNIV HSC NEW ORLEANS	Mature mouse cochlea culture model for physiological inv	71,500
R21DC005514–01	WATSON, GLEN M	UNIVERSITY OF LOUISIANA AT LAFAYETTE	Target Proteins for Linkages in Membranes of Hair Cells	62,320

R21DE015051–01	HAGENSEE, MICHAEL E	LOUISIANA STATE UNIV HSC NEW ORLEANS	Prevalence of HPV in the Oral Cavity of HIV+ Individuals	206,700
R21DK057390–02	PARTOSEOEDARSO, ELITA R	LOUISIANA STATE UNIV HSC NEW ORLEANS	VAGAL GASTRIC MOTOR CONTROL IN MICE	143,000
R21ES012026–01	REISER, JAKOB	LOUISIANA STATE UNIV HSC NEW ORLEANS	Protein trapping tools for mammalian cells	213,000
R21GM065612–01	POLLOCK, DAVID D	LOUISIANA STATE UNIV A&M COL BATON ROUGE	Protein sequence, structure, and computational analysis	138,348
R21NS042736–01	BRISKI, KAREN P	UNIVERSITY OF LOUISIANA AT MONROE	Microscopic Quantitative Mapping Ion Flux in Rat Brain	99,500
R21NS043974–02	EHRLICH, MELANIE	TULANE UNIVERSITY OF LOUISIANA	FSHD Syndrome: DNA Repeats, Methylation, & Chromatin	185,625
R21RR015016–03	MURRAY, KERMIT K	LOUISIANA STATE UNIV A&M COL BATON ROUGE	MADLI Mass Spectrometry for Microfluidic Chip Detection	89,570
R24CA084625–03	SOPER, Steven A	LOUISIANA STATE UNIV A&M COL BATON ROUGE	MICRO–INSTRUMENT PLATFORMS FOR GENETIC–BASED ANALYSES	537,986
R24CA084625–03S1	SOPER, Steven A	LOUISIANA STATE UNIV A&M COL BATON ROUGE	MICRO–INSTRUMENT PLATFORMS FOR GENETIC–BASED ANALYSES	33,075
R24HL060808–05	STRONG, JACK P	LOUISIANA STATE UNIV HSC NEW ORLEANS	PDAY CARDIOVASCULAR SPECIMEN AND DATA LIBRARY	131,915
R24RR015395–01A2	BAVISTER, BARRY D	LOUISIANA STATE UNIV–UNIV OF NEW ORLEANS	EMBRYO TECHNOLOGIES FOR PROPAGATION OF RHESUS MONKEYS	250,176
R24RR016986–01A1	Marx, Preston A	TULANE UNIVERSITY OF LOUISIANA	AN IMPROVED MACAQUE MODEL FOR SIV AND SHIV	683,168
R25CA047877–15	LOPEZ–S, ALFREDO	LOUISIANA STATE UNIV HSC NEW ORLEANS	SHORT RESEARCH EXPERIENCES IN CANCER	66,965
R25CA087994–03	GREGORY, PAULA E	LOUISIANA STATE UNIV HSC NEW ORLEANS	SCIENCE FOR THE NEW MILLENNIUM–-HS CANCER RES PARTNER	63,334
R25GM060926–01A2	STEVENS, CHERYL L	XAVIER UNIVERSITY OF LOUISIANA	MBRS RISE Program at Xavier University	137,138
R25MH058560–05	Duhon, Stacey A	GRAMBLING STATE UNIVERSITY	NIMH HONORS MINORITY HIGH SCHOOL PROGRAM AT GSU	26,001
R29CA076186–05	MEYERS, SHARI L	LOUISIANA STATE UNIV HSC SHREVEPORT	MOLECULAR MECHANISM OF TRANSFORMATION BY AML1/ETO	101,500
R29DC003280–05	Garcia, Meredith M.	TULANE UNIVERSITY OF LOUISIANA	PROTEIN KINASE C IN CENTRAL AUDITORY PLASTICITY	102,566
R29ES009055–05	MILLER, CHARLES A	TULANE UNIVERSITY OF LOUISIANA	ARYL HYDROCARBON RECEPTOR STRUCTURE AND INTERACTIONS	94,724
R29EY012204–05	GLEASON, EVANNA L	LOUISIANA STATE UNIV A&M COL BATON ROUGE	METABOTROPIC GLUTAMATE RECEPTORS ON AMACRINE CELLS	99,231
R29HD036421–06	KUBISCH, HANS M	TULANE UNIVERSITY OF LOUISIANA	MARKER ASSISTED SELECTION OF BOVINE BLASTOCYSTS	152,674
R37AG006168–17	JAZWINSKI, S MICHAL	LOUISIANA STATE UNIV HSC NEW ORLEANS	CELLULAR AGING IN A YEAST MODEL SYSTEM	327,656
R37DK032089–21	BRAY, GEORGE A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	DIETARY OBESITY	308,966
R37DK036013–16	ORLANDO, ROY C	TULANE UNIVERSITY OF LOUISIANA	ESOPHAGEAL CYTOPROTECTION—AGENTS AND MECHANISMS	215,096
R37MH051853–09	MCCANN, SAMUEL M	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	MECHANISM OF ACTION OF CYTOKINES ON BRAIN AND PITUITARY	290,105
R43CA094566–01A1	MORGAN, LEE R	DEKK–TEC, INC.	Clinical Development of 4-Hydroperoxyifosfamide	185,641
R44CA085021–03	MORGAN, LEE R	DEKK–TEC, INC.	DERIVATIVES OF DEMETHYLPENCLOMEDINE:ANTICANCER AGENTS	122,592
R44GM061508–02	SINHA, SUDHIR K	RELIAGENE TECHNOLOGIES, INC.	Dimorphic ALU repeats- Application in identity testing	469,306
R44NS038358–02	NARDUCY, KENNETH W	ST CHARLES PHARMACEUTICALS	Development of Novel Therapeutics for Postsurgical Pain	435,340
S06GM008008–31	STEVENS, CHERYL L	XAVIER UNIVERSITY OF LOUISIANA	MBRS SCORE PROGRAM AT XAVIER UNIVERSITY	761,051
S06GM008025–29	CHRISTIAN, FRED A	SOUTHERN UNIV A&M COL BATON ROUGE	MBRS SCORE PROGRAM AT SOUTHERN UNIVERSITY–BATON ROUGE	44,708
S07RR018185–01	WHELTON, PAUL K	TULANE UNIVERSITY OF LOUISIANA	Technology for Electronic Submission of IRB Protocols	123,500
S10RR016963–01	VEAZEY, RONALD S	TULANE UNIVERSITY OF LOUISIANA	High-speed cell sorter	427,553
S11ES009996–04	BLAKE, ROBERT C	XAVIER UNIVERSITY OF LOUISIANA	ALTERATION OF GENE REGULATION BY ENVIRONMENTAL COMPOUNDS	593,981
S11ES010018–04	MUGANDA, PERPETUA M	SOUTHERN UNIV A&M COL BATON ROUGE	CELLULAR & MOLECULAR TOXICOLOGY OF BUTADIENE	985,060
S21MD000231–01	FRANCIS, NORMAN C	XAVIER UNIVERSITY OF LOUISIANA	Xavier Pharmacy Endowment for Minority Health	5,000,000
T32AA007577–03S1	BAGBY, GREGORY J	LOUISIANA STATE UNIV HSC NEW ORLEANS	BIOMEDICAL ALCOHOL RESEARCH TRAINING PROGRAM	49,758
T32AA007577–04	BAGBY, GREGORY J	LOUISIANA STATE UNIV HSC NEW ORLEANS	BIOMEDICAL ALCOHOL RESEARCH TRAINING PROGRAM	273,978
T34GM007716–24	BIRDWHISTELL, TERESA T	XAVIER UNIVERSITY OF LOUISIANA	MARC U*STAR Training Program at Xavier University	534,181
T34GM008714–04	HIMAYA, M A	GRAMBLING STATE UNIVERSITY	MARC U STAR at Grambling State University	278,345

GRANT NUMBER	NAME	ORGANIZATION	TITLE	AWARDED
T34MH017102–20	DUHON, STACEY A	GRAMBLING STATE UNIVERSITY	NIMH COR HONORS UNDERGRADUATE PROGRAM AT GSU	227,971
U01AG020478–01	RAVUSSIN, ERIC	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	Metabolic Adaptations to Two Year Caloric Restriction	1,432,621
U01AG020478–01S1	RAVUSSIN, ERIC	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	Metabolic Adaptations to Two Year Caloric Restriction	147,000
U01AG020478–01S2	RAVUSSIN, ERIC	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	Metabolic Adaptations to Two Year Caloric Restriction	915,000
U01AI032913–10	VAN DYKE, RUSSELL B	TULANE UNIVERSITY OF LOUISIANA	Tulane/LSU Pediatric AIDS Clinical Trials Unit	815,476
U01AI038844–04S3	Lertora, Juan J. L.	TULANE UNIVERSITY OF LOUISIANA	AIDS CLINICAL TRIALS UNIT	285,956
U01AI042178–11	MUSHATT, DAVID M	TULANE UNIVERSITY OF LOUISIANA	LOUISIANA COMMUNITY AIDS RESEARCH PROGRAM (CPCRA)	853,801
U01CA083014–04	ZAKRIS, ELLEN L	TULANE UNIVERSITY OF LOUISIANA	TULANE AIDS–ASSOCIATED MALIGNANCY CONSORTIUM	154,826
U01DK048377–09	BRAY, GEORGE A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	NIDDM PRIMARY PREVENTION TRIAL (DPT 2)	304,921
U01DK056990–04	BRAY, GEORGE A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	Clinical Center for Look AHEAD: Health in Diabetes	1,312,399
U01DK056990–04S1	BRAY, GEORGE A	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	Clinical Center for Look AHEAD: Health in Diabetes	7,350
U01DK060963–02	HE, JIANG	TULANE UNIVERSITY OF LOUISIANA	Clinical Center for Prospective Cohort Study of CRI	316,100
U01DK060963–02S1	HE, JIANG	TULANE UNIVERSITY OF LOUISIANA	Clinical Center for Prospective Cohort Study of CRI	250,000
U01HD031315–09	WILSON, JOHN T	LOUISIANA STATE UNIV HSC SHREVEPORT	PEDIATRIC DRUG EVALUATION RESOURCE	383,323
U01HD031315–09S1	WILSON, JOHN T	LOUISIANA STATE UNIV HSC SHREVEPORT	PEDIATRIC DRUG EVALUATION RESOURCE	178,033
U01HD040470–02	ABDALIAN, SUE E	TULANE UNIVERSITY OF LOUISIANA	NEW ORLEANS ADOLESCENT MEDICINE TRIALS UNIT	762,602
U01HL060571–05	HARSHA, DAVID W	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	PREMIER—LIFESTYLE INTERVENE FOR BLOOD PRESSURE CONTRL	163,892
U01HL066855–03	Webber, Larry S.	TULANE UNIVERSITY OF LOUISIANA	TRIAL OF ACTIVITY FOR ADOLESCENT GIRLS (TAAG)	763,926
U01HL072274–01	LEISSINGER, CINDY A	TULANE UNIVERSITY OF LOUISIANA	Hemostasis Clinical Research Network Protocols	300,000
U01HL072507–01	HE, JIANG	TULANE UNIVERSITY OF LOUISIANA	Genetic Epidemiology of Blood Pressure Intervention	1,432,730
U01HL072510–01	LEFEVRE, MICHAEL	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	Diet, genetics, and CVD risk factor response in Blacks	2,098,725
U10CA035272–19	KARDINAL, CARL G	OCHSNER CLINIC FOUNDATION	OCHSNER COMMUNITY CLINICAL ONCOLOGY PROGRAM	467,005
U10CA058658–10	MILLS, GLENN M	LOUISIANA STATE UNIV HSC SHREVEPORT	SOUTHWEST ONCOLOGY GROUP	324,550
U10CA063845–08	Gilbert, Jill	LOUISIANA STATE UNIV HSC NEW ORLEANS	LSUHSC Minority Based Community Clinical Oncology	211,735
U10NS044471–01	RAO, JAYARAMAN	LOUISIANA STATE UNIV HSC NEW ORLEANS	Nicotine and Neuroprotection in Parkinson's Disease	104,197
U19AI045511–03S1	BEIER, JOHN C	TULANE UNIVERSITY OF LOUISIANA	AFRICAN MALARIA VECTORS	76,005
U19AI045511–04	BEIER, JOHN C	TULANE UNIVERSITY OF LOUISIANA	AFRICAN MALARIA VECTORS	680,483
U19AI045511–04S1	BEIER, JOHN C	TULANE UNIVERSITY OF LOUISIANA	AFRICAN MALARIA VECTORS	40,189
U24RR018111–01	BOHM, RUDOLF P	TULANE UNIVERSITY OF LOUISIANA	ESTABLISHMENT AND EXPANSION OF A SPF RHESUS COLONY	769,149
U42RR015087–03	ROWELL, THOMAS J	UNIVERSITY OF LOUISIANA AT LAFAYETTE	ESTABLISHMENT/MAINTENANCE OF BIOMEDICAL RESEARCH COLONY	843,593
N01NS992302	ROWELL, THOMAS J	UNIVERSITY OF LOUISIANA AT LAFAYETTE	SLOW, LATENT & TEMPERATE VIRUS INFECTIONS	1,171,906
N01HR16150	DEBOISBLANC, BENNETT	UNIVERSITY OF LOUISIANA AT LAFAYETTE	ADULT RESPIRATORY DISTRESS SYNDROME STUDY	125,337
N01AO12747	HASSELSCHWERT, DANA	UNIVERSITY OF LOUISIANA AT LAFAYETTE	MAINTENANCE OF A SPF PIGTAIL BREEDING COLONY	1,922,466
N01AO22751	FONTENOT, BABETTE	UNIVERSITY OF LOUISIANA AT LAFAYETTE	BREEDING,HOUSING AND MAINTENANCE OF RHESUS MACAQUES IN SUPPORT OF AIDS.	1,349,886
N01AO22754	HASSELSCHWERT, DANA	UNIVERSITY OF LOUISIANA AT LAFAYETTE	LEASING OF CHIMPANZEES FOR THE CONDUCT OF RESEARCH	1,360,000
U42RR016026–02	BLANCHARD, JAMES L	TULANE UNIVERSITY OF LOUISIANA	SPECIFIC PATHOGEN FREE INDIAN RHESUS MONKEY COLONY FOR A	1,311,873

U45ES010664–03	WRIGHT, BEVERLY H	XAVIER UNIVERSITY OF LOUISIANA	WORKER HEALTH AND SAFETY TRAINING COOPERATIVE AGREEMENT	993,562
TOTAL FY 2002				117,481,005

BIOTERRRORISM

Senator SPECTER. Mr. Secretary, coming back to the bioterrorism, the budget has a figure of $3.6 billion. How is help going to be given to the States on dealing with bioterrorism? I have traveled my State. I know my colleagues have traveled their States. But there are no funds which are being devoted. The University of Pittsburgh Medical Center, for example, has a very elaborate system where they have plans to bring people in in the event of bioterrorism attack, showers, quarantines, response to anthrax or smallpox or whatever else may occur. But what is being done about distributing funds from the Federal Government to the States?

Secretary THOMPSON. Last year, Senator, we had $918 million that we could send out for the State departments and local health departments and communities for biopreparedness. And we had an additional $125 million that was sent out for hospitals in order to find ways in which they might be able to expand their surge capacity, and that was distributed on a formula throughout all of the States in America.

But in addition to that, we asked them to make some planning because we knew that we were going to ask for some additional money in fiscal year 2003, which is $518 million, which has been appropriated, less a reduction, I think, of about 1 percent in the appropriation language. So there is $518 million, less that reduction for balancing the budget, that is going to be sent out to the hospitals based upon their plans.

Senator SPECTER. How much money is that again?

Secretary THOMPSON. $518 million.

Senator SPECTER. Is that remotely enough?

Secretary THOMPSON. We are expecting that to be replicated again this year in fiscal year 2004 and fiscal year——

Senator SPECTER. Do you have an estimate on how much money it will take?

Secretary THOMPSON. We have lots of estimates, but I cannot tell you off the top of my head right now exactly. I know it is a lot more than——

Senator SPECTER. Could you provide for us what it will cost? It seems to me that to adequately prepare the hospitals in America for bioterrorism is a gigantic figure. I know you are working on it. But would you provide for the subcommittee what it is?

Secretary THOMPSON. Sure, absolutely.

[The information follows:]

BIOTERRORISM

We are providing $518 million, roughly the full authorization level in Section 319C–1 of the Public Health Service Act, to improve and expand the capacity of our Nation's hospitals to respond to biological, chemical, and radiological terrorist attacks and situations involving large scale casualties. These funds will supplement the $515 million appropriated for these activities in fiscal year 2003, and $135 million in fiscal year 2002, bringing the total to $1.2 billion over 3 years—a significant investment. The fiscal year 2003 appropriation for the District of Columbia also included $10 million for related hospital preparedness activities. We believe that our investment is significantly contributing to meeting the need of hospitals to adequately prepare to deal with bioterrorism. We are working with the States, the American Hospital Association, American Association of Poison Control Centers, American College of Emergency Physicians, American Academy of Pediatrics, National Association of EMS Physicians, National Association of State EMS Directors,

Association of State and Territorial Health Officials, National Rural Health Association, National Association of Community Health Centers, National Association of Social Workers, and the American Nurses Association. Each State has developed a plan for preparing their hospitals and other health care facilities. These funds will be expended consistent with these State plans and assessments.

Senator SPECTER. So we have some idea as to what it is and how we are getting there.

Mr. Secretary, there is an enormous——

Secretary THOMPSON. If I could.

Senator SPECTER. Yes, go ahead.

Secretary THOMPSON. Pennsylvania has got an obligation of $33 million, and they have only drawn down $9.5 million. There are still $23 million undrawn for the State of Pennsylvania as of right now.

Senator SPECTER. That is the 19 percent drawdown you have talked about?

Secretary THOMPSON. Yes. Pennsylvania has drawn down a little bit more, but it still has $23 million.

Senator SPECTER. And that is a simple matter for them to draw it down?

Secretary THOMPSON. Yes. But this is before we sent out the additional $1.5 billion, which we are in the process of sending out right now.

Senator SPECTER. Well, that is important to move ahead on, and we will assist on that.

Secretary THOMPSON. Thank you.

Senator SPECTER. I was about to say, Mr. Secretary, there is enormous anxiety everywhere as to what is going to happen in the course of the next several days. You are in the command center. You have the responsibility for a big chunk of preparedness on bioterrorism. Can you provide any insights as to what people might expect as we have the countdown to war?

Secretary THOMPSON. We have, of course, gone from code yellow to code orange, and there is a possibility we will be going to code red. I am not sure about that, but there is a possibility.

Senator SPECTER. Are you consulted? Is your Department a party to that determination?

Secretary THOMPSON. The determination is by the Department of Justice and the Department of Homeland Security, but we have very close cooperation and communications with both of those Departments. We work very closely with them.

What we are anticipating is, Senator, that there could definitely be attacks, bioterrorism, chemical, radiological, nuclear, whatever the case may be. We have placed some of our DMAT teams on alert so that they can be moved very quickly.

Senator SPECTER. When you say radiological, what do you mean by that?

Secretary THOMPSON. That is a dirty bomb, a nuclear bomb.

We have divided up the country into 10 regions. We have approximately 8,000 medical doctors, nurses, morticians, and veterinarians that can be called up. We have 600 tons of medical supplies and equipment strategically located in 12 sites around America that we can move to any city in America within 7 hours.

Senator SPECTER. And what kind of paraphernalia do you have in these sites?

Secretary THOMPSON. All kinds of things from masks, to antibiotics, to antidotes, to mark I kits for chemicals. Vaccines are in a different place. There are also masks, other kind of equipment to be used, stretchers and so on, if need be. They are strategically located in 12 sites around America.

Senator SPECTER. Do you have adequate resources to handle that particular issue?

Secretary THOMPSON. We think at this point in time we do, Senator. I think we could allay your concerns tremendously if you would come over and just take a look at what we have, how we are set up to deploy people, equipment, and supplies, and how we are able to monitor everything and stay in communication with every State and local health department.

In our GIS, we are I believe the only one that has in our database every hospital, every fire station, every police station, all of the first responders. We have all the railroad lines in our GIS system. We know daily how many beds are available in each hospital. We can set up plume modeling for any kind of chemical or any kind of gas that is exploded. On a street level, we have every street in America in our GIS database so that we can——

Senator SPECTER. Every street in America?

Secretary THOMPSON. Every street in every city.

Senator SPECTER. Okay. I am going to come take a look.

Secretary THOMPSON. I think you would be very impressed by what we have done.

Senator SPECTER. I want to see the markings on Senator Craig's street.

I want to see how closely you have him tabbed.

Senator CRAIG. Mr. Chairman, when you get ready to go, I will go with you. I would like to see that too.

Secretary THOMPSON. It is absolutely amazing. I would love to have you come over.

Senator CRAIG. The problem is my hometown does not have any streets.

It has a road that goes to it.

Secretary THOMPSON. We have the capacity in our communication room to hook up to any one of 4,000 local TV stations across America so that if something would happen in Idaho, we could bring up the TV stations and find out what is happening on site in that particular area.

Senator CRAIG. That is very impressive.

Mr. Secretary, were you involved in a briefing with the Governors in the last couple of days?

Secretary THOMPSON. No, I was not.

Senator CRAIG. Mr. Chairman, in relation to your express concern here—and it is mine—as to the next 24 to 48 hours, Homeland Security and I believe CIA were involved in a briefing with all of our Governors in the last 24 hours that my Governor tells me was the most comprehensive detail he has yet had and he was very pleased about it. That kind of communication is improving greatly, and the ability now for you all to tie, as you are telling us you can, is a very real advancement.

Secretary THOMPSON. I think if you came over, you would be very impressed.

Senator CRAIG. I will do that. I will make a point to do it.

Secretary THOMPSON. We are in weekly, if not daily, contact with all the State health departments through CDC and through our communication room. So we are keeping everybody very well up to speed as to what is going on, Senator.

Senator CRAIG. Thank you.

OBESITY AND LIFESTYLE

Senator SPECTER. On the issue of obesity and lifestyle, this subcommittee held a hearing in San Francisco during the last recess and developed a lot of fascinating information. A big part of the problem may originate in fast foods where people are encouraged to eat foods which are very harmful, so it is said. There recently was a lawsuit against McDonald's which was dismissed.

What can be done by way of so-called jawboning to try to get fast food chains to do something about the kind of food they serve?

Secretary THOMPSON. I held a meeting, Senator, with several members of the fast food industry and the national restaurant organization. We had a difficult but I think productive meeting and got pledges from them that they would be helpful in trying to put healthier items on their menu.

[The information follows:]

FAST FOOD INDUSTRY

Secretary Thompson has made it clear that obesity is a problem that requires a multi disciplinary approach to address this unprecedented epidemic. HHS has reached out to both public and private organizations, including the fast food industry to find unique ways to establish partnerships that will impact this epidemic.

HHS has strongly encouraged the fast food industry to provide healthy choices on menus, aggressively market those choices to consumers, and reduce portion sizes.

Senator SPECTER. Anything concrete? Anything specific?

Secretary THOMPSON. Nothing specific at this point in time. That is why we are going to try and have this prevention summit. I believe it is in April. I will let you know the date, Senator, and hopefully you can come.

Senator SPECTER. What do you think of the litigation on the analogy to smoking, to dangers in smoking? I see the Justice Department just this week has taken a very strong position about fraud on the tobacco companies in enticing juveniles to smoke, put an enormous figure, into the hundreds of millions of dollars. Is there any analogy to subjecting people to the risks of adverse health from foods which are unhealthy?

Secretary THOMPSON. Well, as you know, there was a lawsuit started and it was dismissed. I am not sure that that is the most correct way to go, Senator. I think that a better way to do it is to bring them in and try and convince them to do it. I spent a half a day at Hamburger University, which is at the McDonald's campus in northern Illinois, and they were willing to be quite supportive to try and get healthier items on their menus.

Senator SPECTER. Well, we would be very interested to see what results you have.

Let me move to a couple of other subjects quickly and terminate the hearing because we have kept you here a long time.

TAX CREDITS FOR HEALTH INSURANCE

You talk about tax credits for health insurance. Is that an administration position?

Secretary THOMPSON. No. It is mine.

Senator SPECTER. It would be a good idea. We see the number of uninsured Americans. If you had a tax credit, that would be a very effective way of dealing with the issue.

Senator CRAIG. Mr. Chairman?

Senator SPECTER. Senator Craig.

Senator CRAIG. Mr. Secretary, you did tie that comment, though, to long term, did you not?

Secretary THOMPSON. Yes.

Senator CRAIG. Thank you. I agree with both, but clearly to introduce long-term health care insurance into our economy would be a tremendous advantage to get people investing in insurance that carries them through to death of that kind.

Secretary THOMPSON. I would also like to see health insurance charge lower premiums for people that lead healthier lifestyles like they do on automobiles.

Senator CRAIG. I agree.

Secretary THOMPSON. It is something that we could work on.

TAX CREDITS ON MALPRACTICE INSURANCE

Senator SPECTER. On the issue of tax credits, one of our colleagues in the Senate is talking about a tax credit on malpractice insurance. We had a hearing last week on that subject, and this is a new idea which is being considered. What would you think of that, which could be tailored to the areas which have the greatest problem at the present time?

Secretary THOMPSON. Senator, I have not looked at it. I am not knowledgeable about that subject. I would like to read it. It seems like it has got some possibilities.

Senator SPECTER. We had a lengthy hearing, Mr. Secretary, and we had responses from Deputy Secretary Claude Allen. I would appreciate it if you could find the time to review Secretary Allen's testimony and give a response to the subcommittee as to whether you think it was adequate in answering the questions which we posed.

Secretary THOMPSON. Okay.

Senator SPECTER. I would appreciate that.

[The information follows:]

TAX CREDIT ON MALPRACTICE INSURANCE

I do not believe that the crisis can be fixed by giving doctors tax credits to help pay the cost of malpractice insurance. This would simply require the taxpayers to pay even more for the cost of the excesses of the litigation system. They already are paying $70 billion as patients and insured for the problems caused by the litigation system. At the same time, a tax credit would do nothing to address the underlying problems of the litigation system. It would feed, not fix, the broken litigation system. We believe the Congress should enact reasonable reforms such as those passed by the House in H.R. 5.

MEDICAL LIABILITY

Senator SPECTER. In looking at medical liability—and there is a lot of concern. Pennsylvania has a very, very serious problem. Quite a number of States do. When we talk about frivolous law-

suits, we are talking about a subject matter which I think really is containable. We have had testimony that 70 percent of the lawsuits are won, but even if the defendants win, the cost of litigation is so high that it boosts rates. There are ways to deal with that, sanctions on lawyers, requirement of a certification by doctors from a panel that there is something to be submitted to the court.

We have taken a look at the insurance industry. There was a problem in Texas on homeowners insurance. Nobody could buy homeowners insurance because there had been so many hurricanes and the insurance companies had invested the money and the stock market had gone down.

MEDICAL ERRORS

The medical errors issue. We are anxiously awaiting your report on medical errors to see to what extent that impacts. When you talk about caps, you are on a very sensitive subject, but I think there is some latitude, if it is done carefully. I think there has to be some exclusion for cases like the transplant victim in North Carolina, something which is catastrophic or something like we had a witness testify about a double mastectomy which was erroneous. They got the wrong x-ray slides. There is a lot of complaint and understandably about the lottery, so to speak, with minor cases coming in with gigantic verdicts.

Would you think that there could be some careful pruning? There are some State laws on liability, for example, of governmental units which exclude what they call catastrophic cases, permanent impairment of bodily function or death or major disfigurement. Would you think that would be an appropriate line to make?

Secretary THOMPSON. Senator, the administration feels very strongly that we need to have cap on noneconomic damages, but what you are looking at are many new ideas that certainly should be explored. I am willing to look at each and every one of them.

We are looking at something in the Department that we are going to try administratively and that is first offer. We do not know if it is going to work, but we are going to try in some of our cases to be able to offer money to a patient that has been harmed and pay for their expenses. We are trying to set it up administratively so that we could do it outside of litigation. They still would have the right to appeal.

Senator SPECTER. First offer by the Government, by the Department of Health and Human Services?

Secretary THOMPSON. That is correct. To see if we could somehow show that this is a new procedure. We are working with a professor I believe in North Carolina that has come up with this new mechanism on how we might be able to reduce litigation.

Senator SPECTER. Well, we would be interested to see the details on that.

Senator Craig, anything more?

Senator CRAIG. I do not have anything more. Thank you, Mr. Secretary, Mr. Chairman.

Senator SPECTER. Thank you very much, Mr. Secretary.

Secretary THOMPSON. Thank you, Senator.

Senator SPECTER. We will be working with you on this.

Secretary THOMPSON. Please do, and I appreciate it.

Senator Craig, thank you.

Senator CRAIG. Thank you.

Secretary THOMPSON. Thank you for your leadership on long-term. That is great.

PREPARED STATEMENT RECEIVED

Senator SPECTER. We have received the prepared statement of Senator Thad Cochran which will be placed in the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, thank you for holding this hearing on the 2004 budget for the Department of Health and Human Services. At this important time, we must ensure that we are setting clear priorities and investing wisely in the health and safety of all Americans. Thank you, Secretary Thompson for appearing before us today and for the excellent job you are doing as Secretary of HHS. I appreciated your visit to my state last May.

As we consider the 2004 budget, I think our first priority should be protecting the safety of our country's citizens. While the defense of our country comes frist, we must make increased investments in the health infrastructure of our nation. I am pleased to see the overall commitment of over $3.5 billion in research and infrastructure funding aimed at detecting and responding to a national emergency. This is a wise investment because these public health capacities and research findings improve our ability to respond to naturally occurring disease outbreaks even if no bioterrorist incident ever occurs.

We must also remember that cooperation and coordination between HHS and the Departments of Homeland Security, Agriculture, and Defense are vital to our response to a biological or chemical attack. We must build these relationships before an attack occurs.

We must not forget that our nation also faces other pressing health problems. The biomedical research conducted by HHS has dramatically improved the health of Americans. While the amazing growth of the NIH's budget could not be sustained, the President's budget provides a 2 percent increase. I hope this figure can be increased so that we continue the progress NIH and other agencies have made in understanding disease.

The funding for the Centers for Disease Control also provides for important public health research, especially with regard to chronic diseases. The budget provides an additional $100 million for the prevention of chronic diseases. This initiative has the potential to provide tremendous returns. However, we must not shortchange the other important areas such as infectious disease, birth defects, and occupational injuries.

We must also continue to make investments in clinical and research technology. NIH has been leading this effort. Biomedical technology provides the great promise in the detection, treatment and prevention of disease. It also provides our best opportunity to confront the challenges of medical errors and patient safety.

The budget also provides for those in our country most in need of health. The $1.6 billion provided for Community Health Centers will create access to health care for over 1 million Americans, according to the Department.

The budget also provides $47 million for the Office of Minority Health and $193 million for the National Center for Minority Health and Health Disparities. While it is important for us to continue to increase these funding levels, it is also important for us to continue to work to make sure that this research and outreach takes place in those areas of the country where it is most needed.

Mr. Secretary, thank you for the leadership you continue to provide. We look forward to helping you as you oversee the vital programs that provide us a safe and healthy country.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

MEDICAID DRUG REBATE PROGRAM

Question. You are proposing a Medicaid drug rebate program that is estimated to save $13.2 billion over the next ten years, and save states a similar amount. How much do you estimate will be saved in Fiscal 2004?

Answer. CMS actuaries have estimated that the adjustment to the Medicaid drug rebate formula will save the Federal Government $800 million in fiscal year 2004.

Question. Could this component of Medicaid reform be enacted as a separate, free-standing initiative? Provide bill language that would accomplish this rebate program.

Answer. Yes this legislation could be enacted as a separate free-standing initiative. The savings I just gave you reflect what would be the case without Medicaid and SCHIP modernization. As we have stated previously there are some problems with the current formulation of the drug rebate. There have been a number of suggestions on how the rebate formula might be improved. One option suggested was to change the rebate formula from the difference between Average Manufacturer's Price (AMP) and best price, to the difference between Average Wholesale Price (AWP) and best price. Another was to simply set the rebate equal to a percentage of AMP. Both of these proposals, and others, would save us money. We wish to work with Congress to come up with the plan that best advances the interests of the Federal Government and the American taxpayer.

MEDICAL LIABILITY REFORM LEGISLATION

Question. Last week, you issued a press release applauding the House of Representatives for passage of Medical Liability Reform Legislation. The statement said you looked forward to working with the Senate to pass complementary legislation this year. I chaired a hearing on this subject last week, and the matter of capping non-economic awards at $250,000, without exceptions, for egregious cases, was very controversial. Do you have a compromise plan to gain bi-partisan support in the Senate?

Answer. The Department's report entitled: "Addressing the New Health Care Crisis: Reforming the Medical Litigation System to Improve the Quality of Health Care," shows how problems associated with medical litigation have worsened significantly in the past year. Premiums charged to specialists in 18 states without reasonable limits on non-economic damages increased by 39 percent between 2000 and 2001. Premiums in these states have since gone up an additional 51 percent. This report also documents the spiraling cost of insurance for health care providers, which is impairing patients' access to care, as well as the cost and quality of care.

Therefore, reasonable caps on non-economic damages increase doctors; hospitals' and nursing homes' ability to stay in business, which leads to greater access to care. In addition, caps on non-economic damages reduce the growth of medical liability costs and insurance premiums. Over the last two years, states with limits of $250,000 or $350,000 on non-economic damages have seen increases in premium quotes for specialists increase only 18 percent. States without reasonable limits on non-economic damages, in states representing almost half of the entire U.S. population, have seen average increases of 45 percent. Since California implemented a reasonable cap on non-economic damages and other critical procedural reforms 25 years ago, liability premiums have increased by less than one-third as much as in the rest of the country. It is important to implement caps at $250,000 for the sake of affordability and access to quality health care.

MEDICARE PAYMENT POLICY

Question. MedPAC considers the implementation of a transition method as an important aspect of any new payment system design when establishing its framework for assessing Medicare payment policy issues. Payment corridors, hold-harmless methods, blend approaches as well as phase-in periods have been adopted in different circumstances in order to cushion the impact of payment changes on individual providers and prevent service disruptions. Did CMS consider incorporating any of these methods when designing its new outlier policy?

Answer. Extensive discussions were held on the best approach to solving the problems caused by hospitals exploiting vulnerabilities in the determination of outlier payments.

It must be kept in mind that the goal of Medicare is to make fair and accurate payments for services rendered, these higher payments were made because of a vulnerability in the determination of payments not as a result of the true costs of services provided. The proposed outlier rule will allow CMS to ensure that only hospitals that are truly experiencing higher then expected costs can receive reimbursement.

HOSPITAL COST COMPUTATION

Question. In its September, 1988 rulemaking process, HCFA (now CMS) received a number of comments expressing concern about the timeliness of the data used to compute hospital specific cost-to-charge ratios, the issue that is at the core of the problem addressed by the newly proposed regulatory change. In 1988 some suggested that data from the latest filed cost report be used. CMS dismissed that suggestion stating that Medicare costs are often overstated on the filed cost report and are subsequently reduced by audit; CMS elected to use data from a hospital's final settled cost report to establish the pertinent cost-to-charge ratios. Now CMS is proposing to use information from a hospital's tentatively settled cost reports to calculate hospital specific ratios. To what extent do hospitals costs change between tentative and final settlement?

Answer. Hospital costs can either increase or decrease between tentative and final settlement. When a cost report is received by the FI they ensure the cost report is complete before accepting it. Once the cost report is accepted the FI has 60 days to make a tentative settlement on this cost report. The tentative settlement process usually entails looking at the providers past cost report history and making any necessary adjustment to the current cost report based on prior year data. In order to final settle the cost report, the FI will perform a desk or field review of the cost report. Based on the review, adjustments are made to costs, charges, and reimbursement in order to final settle the cost report. This final settlement represents final payment to the provider.

There is a variation in the change of hospital costs between tentative and final settlement, depending on the areas reviewed and the results of the review. However, it is highly unlikely that the cost from the tentative to the final settled cost reports would change as much as the latest changes in the cost per case (over 12 percent from 2001 to 2002). With this amount of year-to-year change in charges, it is imperative to use the latest available cost-to-charge ratio. Reconciliation at final settlement will take care of any large differences used for payment and the actual ratio.

Question. Is the concern expressed by CMS in 1988 any less valid today?

Answer. No, this issue is still pertinent, filed cost reports have not been reviewed and if necessary audited, and are not an appropriate basis of final payment. For this reason the proposed outlier rule uses tentative cost reports which can include adjustments for "known" issues, to determine the initial payments. Final settlements are used to adjust the initial payments and if necessary an adjustment for the time value of money will be made if the initial payments were inaccurate.

Our goal is always to make the most accurate payment possible. The proposed outlier rule highlights that a change was necessary to prevent hospitals from exploiting vulnerabilities in the determination of outlier payments. Using tentative cost reports will help eliminate a vulnerability in the system, and using the final settled cost reports to determine final payments ensure their accuracy.

MEDICARE DRUG BENEFIT

Question. The President's budget dedicates $400 billion over ten years for targeted improvements and modernization of Medicare, including providing access to subsidized prescription drug coverage. The Senate Budget Resolution also contains a $400 billion reserve fund for Medicare. What would your proposal offer in prescription drug coverage for those who stay in the traditional fee-for-service Medicare program, compared to those who opt for a managed care plan?

Answer. The President's Framework to Modernize and Improve Medicare gives beneficiaries immediate help with their prescription drug bills starting in 2004, for beneficiaries in both traditional fee-for-service and Medicare + Choice plans. A drug discount card will allow all beneficiaries to save 10–25 percent off retail prices on their medicines. Low-income beneficiaries will also get a $600 benefit added to the drug card.

Beginning in 2006, beneficiaries will have three options for their Medicare benefit: Traditional Medicare, Enhanced Medicare, and Medicare Advantage. Under, the first option, Traditional Medicare, beneficiaries could continue receiving their care

through the existing program, while getting a drug discount card that will allow them to save 10–25 percent on their prescription drug bills. For no additional premium, fee-for-service beneficiaries will also get protection from high out-of-pocket drug costs.

Under the second option, Enhanced Medicare, beneficiaries could choose to receive integrated benefits and drug coverage offered through a FFS/PPO plan, like FEHBP or TRICARE. Plans would bid to serve one or more of 10 different regions in the country, and the three best qualified bids in each region would be awarded the opportunity to compete for beneficiaries' business. All beneficiaries in a region would be guaranteed access to all plans serving a region. Beneficiaries who enroll in the plan submitting the middle-priced bid in their region would pay a premium equal to the Part B premium in traditional Medicare. Those choosing the plan with the low-priced bid would receive most of the savings, while those choosing the high-priced bid would pay a supplemental premium. All beneficiaries would pay an additional premium for drug coverage, except for those with low incomes. New benefits in the enhanced package include a combined deductible for Part A & B services, free preventive benefits, and protection from high out-of-pocket medical costs.

Under the third option, Medicare Advantage, beneficiaries could choose to receive the integrated benefits and drug coverage through a managed care plan. Plans in competitive markets would bid to provide the enhanced benefit package. Beneficiaries who select the most efficient plan could share in the premium savings (and possibly pay no premium). Beneficiaries could select a plan without drug coverage if they are satisfied with their current coverage. Like Enhanced Medicare, beneficiaries would pay an additional premium for drug coverage, unless they are low-income.

Question. What additional coverage are you suggesting for preventive health services, such as nutrition education?

Answer. Beneficiaries enrolled in Enhanced Medicare and Medicare Advantage will be able to receive preventive services absolutely free—all current co-pays will be waived. As you may know, the Medicare currently covers screening mammography, screening pap smears and pelvic exams, colorectal cancer screening, prostate cancer screening, glaucoma screening, diabetes self-management, medical nutrition therapy, bone mass measurements, and certain vaccines. The President's Framework promises that the cost of a co-pay will never stand in the way of this potentially life-saving preventive care.

PHYSICIANS' PAY

Question. Congress replaced a 4.4 percent cut this year in Medicare payments for physicians, with a 1.6 percent increase. Will this correction be sufficient to avoid a payment cut in 2004?

Answer. The enactment of the Consolidated Appropriations Resolution (CAR) corrected a statutory flaw in the physician payment formula resulting in multi-year, permanent changes in Medicare expenditures for physicians' services. The CAR provision increased Medicare spending by an estimated $49.6 billion over 10 years by allowing the Centers for Medicare and Medicaid Services (CMS) to revise the fiscal years 1998 and 1999 sustainable growth rates (SGRs) and establish a 1.6 percent update to physician fee schedule rates for March 1 to December 31 in place of the 4.4 percent reduction announced in our December 31, 2002 final rule. The revisions CMS made to the fiscal year 1998 and fiscal year 1999 SGRs allow the physician fee schedule update and SGR system to work as originally intended by the Balanced Budget Act of 1997.

While CMS had previously estimated positive updates for 2004 and later years, we now estimate physician fee schedule updates will be negative for 2004–2007 as a result of higher spending in 2002 for physicians' services and lower real GDP per capita for both 2002 and 2003 than previously estimated. The revisions made to the fiscal year 1998 and fiscal year 1999 SGRs will result in higher physician fee schedule updates for years beginning with 2004 than would have occurred had the CAR of 2003 not been enacted.

Question. What would be the impact on the pay update of excluding the cost of outpatient prescription drugs from the calculation of spending targets for physician services?

Answer. We previously estimated a physician fee schedule update of 1.7 percent for 2004. However, more recent data on actual spending in 2002 and new figures for real per capita GDP changed this estimate to 4.2 percent. We estimate that 44 percent of the change is the result of higher physician spending (other than for drugs). Another 41 percent of change is the result of lower GDP figures for 2002 and 2003. Another 10 percent of the change is the result of higher spending for

drugs and the remaining 5 percent is the result of a small reduction in the estimated Medicare Economic Index (MEI). More information on 2003 spending and real per capita GDP growth will likely change this figure further. The 2004 update would be somewhat less negative if spending for currently covered drugs were removed from the measurement of spending under the 2003 sustainable growth rate.

SMALLPOX VACCINATION PROGRAM

Question. Public health groups are now estimating that the cost of implementing the Smallpox Vaccination Program would range between $154 and $284 per vaccination with a median cost of $204. Does the Administration plan to request an appropriation in the emergency supplemental to provide states with resources so that they may carry out the Smallpox Vaccination Plan without diverting funding from other bioterrorism preparedness or core public health activities?

Answer. We understand that these estimates include a range of costs over and above the direct costs of running an immunization campaign. They include, for example, costs of infrastructure that States should be building with the funds they have already received, costs of the added epidemiologists that funds have been appropriated to cover, and a range of potential indirect costs that State public health departments would not have to pay. CDC is making every effort to assist States in implementing the smallpox vaccination program including providing training to the States, offering technical assistance on administering the smallpox vaccine, and providing education to clinicians, public health groups, and State health officers and organizations. To help implement these plans, CDC and HHS is allowing States to request immediate use of 20 percent of their fiscal year 2003 Bioterrorism grant allocation to be used for immediate needs including implementing the smallpox vaccination program. Although this may not cover all the costs associated with the vaccination, CDC is committed to helping the states in every way possible.

HEAD START

Question. Mr. Secretary, the Administration's budget proposal has identified the fiscal year 2004 as the transfer transition year for Head Start, with the Department of Education taking over administration in 2005. Please provide the specific evidence available that indicates that the Head Start program would better achieve its goals under the stewardship of the Department of Education and therefore support this proposed transfer?

Answer. What I can assure you is that as long as Head Start is in the Department of Health and Human Services, I am going to do everything I possibly can to improve it an make it better.

Over the past two years we have increased our efforts to help Head Start programs enhance school readiness and the development of early literacy skills. In April 2002, the President announced his Good Start/Grow Smart initiative which is designed to assure that every Head Start teacher has the training skills they will need to provide Head Start children the early literacy, language, and numeracy skills they will need to be successful in school. The Strategic Teacher Education Program, knows as STEP, launched last summer, was designed to ensure that every Head Start program and every classroom teacher has a fundamental knowledge of early development and literacy, and of state-of-the-art early literacy teaching techniques. Good Start, Grow Smart calls for not only the improvement and strengthening of Head Start through intense, large-scale efforts in the areas of early language and literacy, but also for a method to track the results of this effort. This fall we will begin implementing the Congressionally mandated assessments of the school readiness of all the four-year old children in Head Start.

Question. What specific actions are being taken by either Department related to this transition year?

Answer. Under the proposal to transfer Head Start to the Department of Education, fiscal year 2004 would be a transition and planning year with implementation in fiscal year 2005. An Interagency Task Force was created in 2001 to consider issues related to the transfer. However, our Department is currently focusing its main efforts on the existing fiscal year 2003 priorities, such as improving early literacy skills in Head Start and developing a national reporting system to better assess child outcomes. This will create a stronger program and we anticipate improvements will continue, should the administration of Head Start be transferred. We are prepared to do the necessary transition planning in fiscal year 2004.

HEAD START FACES AND IMPACT STUDY

Question. Mr. Secretary, in your prepared statement for testimony before this subcommittee on March 19, 2003, you indicated that: "Children in Head Start enter

school further ahead than other economically disadvantaged children. But unfortunately—even after 30 years—Head Start children do not enter school at the same level as more economically advantaged children." This subcommittee has allocated substantial resources for HHS to carry out evaluations of the Head Start program, including FACES and the National Head Start Impact Study. Please provide the subcommittee with a summary of the latest school readiness-related, program quality, and child development findings from the FACES evaluation, as well as a status report on progress made related to the Impact Study.

Answer. The Head Start Family and Child Experiences Survey (FACES) is an ongoing, longitudinal study of Head Start program quality and child outcomes, which currently has two nationally representative cohorts (1997, 2000) and plans for a third. While it does not have a control group of children who are not in Head Start, it does provide important information on program quality over time, and child outcomes from program entry through kindergarten follow-up. FACES uses a sample of classrooms, children, and families that is scientifically representative of all Head Start programs. Child outcomes can be compared with national averages for children of all income levels on a range of standardized assessments. From FACES we find:

The average Head Start classroom is of "good" quality as an early childhood learning environment, consistently over several years of measurement. On the Early Childhood Environment Rating Scale (ECERS), a widely used and well-respected instrument for evaluating quality of early childhood programs, scores can range from 1 (meaning "inadequate") to 7 (meaning "excellent"). In both FACES 1997 and FACES 2000, typical Head Start classrooms received ratings just below 5, or "good."

Few classrooms scored below minimal quality. In FACES 1997, no Head Start classroom in the national sample received a mean ECERS score in the "inadequate" range (1 or 2). In 2000, a few classrooms (two-percent) scored in that range.

The use of integrated curriculum is linked to program quality. In FACES 2000, Head Start programs using the two most widely used integrated early childhood curricula—Creative Curriculum (39 percent) and High Scope (20 percent)—were found to have higher average ECERS language and overall quality factor scores than programs that used "other" curricula.

In addition, FACES 2000 has found that Head Start teachers have higher levels of educational attainment than teachers studied in 1997–1998.

The FACES study allows comparisons of Head Start scores with national averages for children of all income levels. Children enter Head Start with vocabulary scores that are at about the 16th percentile nationally. They made significant progress over the Head Start year, in both the 1997 and 2000 cohorts. For example, English proficient children in FACES 2000 gained 3.8 points in standard scores from 85.3 to 89.1. Methodologists have called such gains "educationally meaningful" and they are greater than the gains made by the typical child of this age, regardless of income level. However, they do not raise Head Start children to the national average in vocabulary scores. Adding in children who were not proficient in English on entry into the program, the average standard score in vocabulary changes from 81.4 to 85.7, representing a gain of 4.3 standard score points over the 2000–2001 year.

In another important literacy area, pre-writing, Head Start children make significant gains relative to national norms (in FACES 2000, 85.1 to 87.1), but are still below national averages. This gain in early writing is slightly smaller than that seen in FACES 1997, although still significant.

In FACES 2000, Head Start children are scoring higher on assessments of letter recognition and book knowledge, areas in which they lagged in 1997–1998. First, Head Start children in FACES 2000 are making more progress in the area of letter recognition than they did in 1997–1998. Their scores meant that children learned the equivalent of 5 additional letters in Head Start and knew an average of 9 letters at the end of the program year. In relation to national norms on the Letter-Word sub-test, Head Start children advanced about as much as the typical preschool-age child, and performed better than the 1997 cohort but still remained below the national norm.

Second, Head Start children are performing better in the area of book knowledge. Book and print concepts do not have national norms available, but in FACES 1997, children did not show advances in this type of knowledge from fall to spring. By contrast, in FACES 2000, mean scores showed a significant gain, from 1.61 in the fall to 2.46 in the spring.

In addition, Head Start children showed growth in social skills and reduction in hyperactive behavior during the Head Start year, according to teacher ratings of behavior. Behavior in Head Start is a predictor of the child's adjustment and performance in early elementary school. Children whose teachers rated them higher on social skills at the end of Head Start were also rated higher by Kindergarten teachers.

Children whose teachers rated them higher on social skills and lower on behavior problems also scored better on cognitive assessments at the end of Kindergarten, even when their Head Start assessments were taken into account.

The Head Start Impact Study is a longitudinal study involving approximately 5,000 three- and four-year old children across 75 nationally representative grantee/delegate agencies (in communities where there are more eligible children and families than can be served by the program). The participating children have been randomly assigned to either a Head Start group (that receives Head Start program services) or a control group (that does not receive Head Start services but may enroll in other available services selected by their parents or be cared for at home). Every effort was made to minimize the burden on individual programs and not to significantly change typical enrollment and recruitment procedures.

Children enrolled in Early Head Start, Migrant Head Start, and programs operated by Tribal organizations, as well as those considered extremely new (i.e., in operation approximately less than 2 years), and those considered severely out of compliance were not included in the study.

Great care was taken to include only programs that were not able to serve all of the eligible children in their community. It was important to have a sufficient number of unserved, eligible children available who could be randomly assigned to a control group, without causing any fewer children to be served by the program than would otherwise be the case. These "saturation" determinations were based on grantee/delegate agencies' own reports of enrollment levels in the fall of 2001, along with other available information.

Data collection began in the fall of 2002 and is scheduled to continue through 2006, following children through the spring of their first grade year. It includes twice yearly in-person interviews with parents, in-person child assessments, annual surveys with care providers and teachers, direct observations of the quality of different care settings, and teacher ratings of children. Data collection will include:

—Individual child data in areas related to school readiness, such as physical well-being and motor development, social and emotional development, approaches to learning, language usage and emerging literacy, cognition and general knowledge;

—Information pertaining to parenting practices, family resources and risk factors, demographic and socio-economic data, and family structure, including parents' descriptions of the types of literacy activities they engage in with children at home;

—Information on structure, process, and quality of Head Start, child care, and school settings through first grade, including teachers' reports on their credentials and experience. Trained observers will assess the quality of different care settings, including assessments of classroom resources and instructional practices; and

—Community level data relating to the availability and means of formal and informal family support services.

An interim report is scheduled for September 2003 and the final report in December 2006.

EARLY LEARNING FUND

Question. The Performance Assessment Rating Tool for the Head Start program, stated that Head Start is not well coordinated with other early education and care programs. However, the Administration has once again proposed to eliminate funding for the Early Learning Fund, a program that seeks to remove barriers to the provision of an accessible system of early childhood learning programs in communities throughout the United States and facilitate the development of community-based systems of collaborative service delivery models characterized by resource sharing, linkages between appropriate supports, and local planning for services. Why does the Administration oppose funding for this program, when it could help states and local communities meet the stated goals of coordination, program improvement, and early care and education services?

Answer. No funds are being requested in fiscal year 2004 for the Early Learning Opportunities Program because the fiscal year 2004 budget provides funding for similar activities in the Department of Education through the Early Reading First program and the Early Childhood Educator Professional Development Grants.

COMPASSION CAPITAL FUND

Question. On December 12, 2002, I was in Philadelphia with President Bush for the White House Conference on Faith-based and Community Initiatives. It was an appropriate setting, as members of the Philadelphia community, in particular Pub-

lic/Private Ventures, have been leaders in the area of faith-based and community initiatives. During his remarks, President Bush highlighted the Amachi program run by Public/Private Ventures, which is serving as the model for the Mentoring Children of Prisoners proposal. As you know, this subcommittee has been very supportive of the faith-based agenda, and just last year, funding for authorized programs received an increase of almost 50 percent. Can you provide the subcommittee with an update on the early lessons learned through grant funding provided by the compassion capital fund, and explain how these lessons are informing planning and implementation for the mentoring program and the President's new substance abuse voucher program, as well as the broader issue of providing an appropriate opportunity for faith and small community based programs to compete for grants programs administered by your Department?

Answer. Although we are in the early stages of implementation for the Compassion Capital Fund, we have already contracted with two research and development firms to begin the necessary work toward performance measurement. Those firms will assess best practices in faith-based organizations through several CCF demonstration project grantees within a sample of eight to 10 intermediary organizations. This effort is part of a comprehensive strategy to develop measures that will not only assess the outcomes of the program's efforts, but will also highlight what strategies work in utilizing this group of organizations to provide services. Using information culled from the assessment of grantees, the contractors will develop and maintain the National Resource Center. The National Resource Center will document programs operated under the Compassion Capital Fund so that practices are measured, and successes emulated or expanded. We will share our findings and experiences across government with interested agencies and programs, including those involved in mentoring programs and the President's substance abuse voucher program.

The Family and Youth Services Bureau (FYSB) within the Administration on Children and Families has been assigned the responsibility for implementing the Mentoring Children of Prisoners program. FYSB has developed a program announcement soliciting applications for grant funding for the program and expects to publish the announcement in the Federal Register early this summer. While no funding has been obligated to date, we anticipate making all grant awards and obligating all funding by September 30, 2003. We expect to make awards to a wide range of eligible applicants, including community and faith-based organizations, State and local units of government, and Tribes.

The President's new substance abuse voucher program, Access to Recovery, is an innovative client-based program to increase access to substance abuse treatment. We recognize there are several pathways to recovery. Access to Recovery will increase substance abuse treatment capacity by allowing an individual to use Federal substance abuse dollars to choose effective treatment organizations, including faith-based organizations. Individuals in need of treatment will first be assessed and then will receive a voucher to pay for an appropriate level treatment. This program emphasizes consumer choice and will reward treatment effectiveness.

More broadly, the department has been busy eliminating the barriers that in the past have prevented faith-based and community-based organizations entry into the Federal funding stream. The Compassion Capital Fund program, for example, supports intermediary organizations to assist faith-based and community organizations in helping faith-based and community organizations expand their capacity to provide needed services to the community. Intermediaries assist these small groups in their efforts to improve effectiveness and organizational management, access funds from diverse sources and manage those funds, develop and train staff, expand the types and reach of social services programs in their communities and develop promising collaboration among organizations dedicated to social service delivery. A National Resource Center is also being established by the Compassion Capital Fund for small faith-based and community organizations. Other accomplishments include making applications more user-friendly, promoting diversity in the grant review panels, and eliminating preference points for organizations previously awarded grants. With these efforts, and the assistance of intermediary organizations, the Department is building a bridge between the federal government and small faith-based and community organizations in the provision of needed services to distressed individuals and communities.

UNACCOMPANIED CHILDREN TRANSFER TO ORR

Question. Mr. Secretary, as you know, section 462 of the Homeland Security Act of 2002 transferred the INS Unaccompanied Alien Children program to the HHS Office of Refugee Resettlement. Please provide the subcommittee with your plan, in-

cluding timeline and budget requirements, for appropriately implementing this provision of the law.

Answer. The UAC program was transferred from INS to the Office of Refugee Resettlement (ORR) on March 1, 2003. Along with this transfer, the fiscal year 2003 funding base of $34.2 million was established for this program. Unobligated fiscal year 2003 funds in the amount of $20.142 million were transferred from INS to ORR on February 28, 2003, in a Determination Order. Much of the transferred balance was committed by INS for shelter care grants and contracts for secure detention prior to the transfer of this program to HHS. These previously existing grants and contracts were transferred to ORR. Twenty-one full-time positions also transferred to ORR.

Consistent with Section 462 of the Homeland Security Act and the Flores v. Reno settlement agreement, ORR will provide care and placement for these children in the least restrictive setting possible. To this end, we are (1) scheduling site visits to review all existing facilities under contract to the former INS, (2) entering into cooperative agreements with the two agencies experienced in the refugee unaccompanied minor program to expand shelter and foster care capacity, and (3) developing training for all staff on the assessment of the children and the facilities.

ORR is currently working with the Department of Homeland Security to finalize a Memorandum of Understanding to specify roles and responsibilities for each agency under the transfer.

The fiscal year 2004 President's Budget includes $34 million in ACF to support the UAC program. This funding level represents an estimate developed before the transfer had been completed. The UAC budget request does not include costs associated with activities not previously performed by INS, newly authorized in the Homeland Security Act, or to reach full compliance with the Flores v. Reno settlement agreement. We look forward to working with Congress to ensure that adequate support is provided for the care of these children.

MEDICARE HEARINGS TRANSFER

Question. What planning and transition activities are being undertaken with SSA to ensure that a timely and smooth transition occurs, if legislation is enacted that transfers the Medicare appeals function effective October 1, 2003, as proposed in the President's budget?

Answer. The Department and SSA have agreed in principle to transfer this function currently performed by SSA's Office of Hearings and Appeals. Negotiations over the details and timing of the transfer are on-going. CMS is preparing a Memorandum of Agreement that will reflect these decisions.

We can transfer the responsibility by October 1, 2003, but to transfer the work itself would be a monumental task to accomplish. For one thing, the existing moratorium on hiring new administrative law judges has not been lifted. For another, CMS's fiscal year 2003 budget did not include funding for appeals reform so they have not been able to begin building the framework of systems and operational support that needs to be in place before this transfer can occur. These activities would normally require 12 to 15 months. Given the delays and costs of the existing process, we would ideally like to have sufficient time and resources to design a process that provides fair and timely hearings for our Medicare beneficiaries.

HEALTH WELLNESS

Question. Under what circumstances would you support funding a chiropractic demonstration project on health (Wellness) enhancement rather than merely the treatment of pain or disease?

Answer. AHRQ has supported research in the area of chiropractic care. One study found that chiropractic care is the most commonly used alternative therapy for back problems, and is as effective as medical care alone for reducing disability and pain in patients with low back pain. To date, the Agency has not supported the wellness aspect of chiropractic care. To continue to build the evidence-base in the area of chiropractic care, AHRQ would give research proposal(s) in this area every consideration under its peer review process.

Question. Given the growing support for lower healthcare costs with evidence—board wellness care. Under what circumstances would you support projects that develop wellness models for health delivery?

Answer. Evidence on effectiveness of care should drive the implementation of wellness models that have been shown to improve health outcomes and quality of life. AHRQ could evaluate the results of biomedical and behavior change research in this area.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

HEAD START

Question. Mr. Secretary, under the Administration's Head Start reauthorization proposal, funding for training and technical assistance in fiscal year 2004 would be reduced by approximately $65,000,000 at the same time that Head Start programs are being asked to implement new child and family literacy and other school readiness activities proposed in the Good Start/Grow Smart initiative, as well as a new outcomes-based accountability system. Please explain specifically how much training/technical assistance funding will be allocated to support these initiatives, as well as identify specifically what costs will be borne by local programs and what source(s) of funds will be available to them to pay for related activities. In addition, what types of training are currently being conducted by local Head Start programs that will have to be foregone in fiscal year 2004 in order to perform these new initiatives?

Answer. The training and technical assistance budget has grown dramatically in the last several years when compared to the number of children served. Since fiscal year 1990, for example, funding for training and technical assistance has grown 300 percent, while enrollment has increased by only 58 percent. Moreover, grantees have received considerable training and technical assistance resources as part of the allocation of quality improvement funds. For example, grantees currently receive $80 million annually for training and related costs designed to increase the number of teachers with college degrees. Allowing the Secretary discretion to best target these funds means that in fiscal year 2004, we will be able to serve almost 10,500 additional disadvantaged children and families in areas of the country which have the greatest unmet need for Head Start services.

The full costs to grantees of implementing the national reporting system will be made available to grantees from the fiscal year 2003 increase, so grantees will not need to reduce any current activities to pay for those costs. Further, much of the early literacy training has been and will continue to be allocated directly to grantees to cover travel and other costs associated with this training, so again there will not be large costs being incurred by grantees.

Grantees, in fiscal year 2004, will continue to be able to address important T&TA issues. We will work with all of our grantees to assure that they have adequate resources to meet their priority needs and will, as necessary, make adjustments in the amount of T&TA resources expended on other areas to assure that this can happen.

CHILD CARE DEVELOPMENT BLOCK GRANT

Question. A recent report by the Southern Regional Initiative on Child Care after interviewing administrators in 15 states and the District of Columbia found that states and localities were collaborating successfully with Head Start in many areas. The Child Care and Development Block Grant currently gives states a great deal of flexibility and they can choose to take advantage of this flexibility to encourage collaboration by aligning their policies with Head Start in areas such as eligibility, eligibility redetermination, reimbursement rates, hours of care, etc. However, the report found that the major barriers to collaboration were not related to Head Start policies but rather were caused by state policies for subsidized child care. How does the administration plan to provide states with the resources necessary to improve their child care policies in order to strengthen collaboration?

Answer. The Administration is committed to promoting collaboration across early childhood programs. Head Start, child care, and other programs can best meet the needs of families and children by working together.

However, we do not believe that barriers to collaboration are solely caused by State policies for subsidized child care. The Southern Institute on Children and Families report found that "respondents generally agreed that polices were not a barrier to collaboration, but a few State child care policies were cited as burdensome to Head Start providers *because they required programs to operate differently* (emphasis added, p.6)." From the perspective of a child care provider wanting to collaborate, Head Start policies might seem burdensome because they are different from child care policies.

There are fundamental differences between the Child Care and Development Fund (CCDF)—which awards monies to States for child care subsidies and quality improvements—and the Head Start program. CCDF supports parental choice by primarily giving families vouchers that they can use with an array of providers in the private child care market while Head Start is a single-design, center-based program operating within prescriptive Federal parameters [Note: Early Head Start (EHS) has a home-based option, a center-based option and a combined option]. CCDF dol-

lars are awarded to States while Head Start grants go directly to local entities. As a condition of eligibility, CCDF requires families to work or attend training or education while Head Start does not. Head Start requires parent involvement in services to their children, CCDF does not. Head Start focuses on serving families below the poverty level, while CCDF concentrates on families transitioning from or at-risk of needing public assistance (some of whom are above poverty). These and other differences make collaboration between the two programs a challenge, but as the Southern Institute report found, not an insurmountable one.

Under President Bush's plan to better prepare children for kindergarten, the Administration has proposed a statutory change that would allow States to better coordinate early childhood programs. States would be given the option to manage Head Start funding, allowing them to coordinate Head Start with other preschool programs in exchange for meeting certain accountability requirements.

Additionally, the Child Care and Head Start Bureaus are taking steps to encourage coordination. For example:

—The Child Care Bureau (CCB) has been charged with implementing aspects of the President's *Good Start, Grow Smart* initiative to help prepare children for school. This includes working with States to develop early learning guidelines, professional development plans, and collaboration plans. CCB's technical assistance effort, including a recent series of regional planning workshops, is designed to meet the needs of the entire array of child care settings and providers and to encourage collaboration across programs.

—The Child Care and Head Start Bureaus jointly fund the Quality in Linking Together (QUILT) technical assistance initiative to support full-day, full-year partnerships among childcare, Head Start, prekindergarten, and other early education programs. QUILT provides training, on-site consultation, written materials, and a website of resources (www.quilt.org), and is particularly adept at strategies to blend or braid funding.

—The Child Care and Head Start Bureaus encourage collaboration between Early Head Start grantees and infant/toddler child care providers, for example, by sponsoring joint training institutes. The Child Care Bureau's new National Infant and Toddler Child Care Initiative will provide technical assistance and consultation to help teams of State stakeholders achieve system-wide improvement in infant and toddler care.

Question. Mr. Secretary, in your prepared statement for your Department's budget hearing on March 19, 2003, with respect to Welfare Reform, you wrote: "we are committed to working with both the House and Senate to ensure legislation moves quickly and is consistent with the President's budget." Before the Senate Committee on Finance, you stated your support for additional child care funding in fiscal year 2004. Given that Senate Budget resolution assumes a discretionary spending increase in the Child Care Development Block Grant of $214 million, while the President requested level funding, and the resolution assumes a mandatory spending increase in the Child Care Development Block Grant of $200 million, will the Administration put forth a budget amendment consistent with these proposals? If not, does the Administration support these increased resources and will it propose appropriate offsets?

Answer. The Administration would support increased child care funding, such as proposed in the House-passed TANF reauthorization bill (H.R. 4), as it is accompanied by strengthened TANF work requirements and improvements to the overall TANF program, and is accommodated within the context of the overall budget.

INDEPENDENT LIVING VOUCHER PROGRAM

Question. Mr. Secretary, I applaud the Administration's awareness of the unique circumstances faced by individuals who will age out of foster care, and its goal to help improve upon this situation with the new Independent Living Voucher program. As you are aware, the Congress provided approximately $42 million in the Department of Health and Human Services Appropriations Act, 2003 to support this new program. Please explain your plan for implementing this new program, specifically how federal funds will be used efficiently and effectively in conjunction with the base Independent Living program and other programs and nonfederal funding streams to better serve the needs such individuals.

Answer. As you mentioned, several purposes of the base Chafee Foster Care Independent Living Program (CFCIP) focus on services and supports to improve the educational outcomes for individuals aging out of foster care. A recent survey indicates States are providing a wide range of services to ensure that youth will stay in and complete high school in order to be eligible for the newly available post secondary education and training vouchers. These services include tutoring, remedial instruc-

tion, the purchase of books, equipment, supplies and school related travel and transportation.

Presently, we are developing guidance to the States to direct the effective implementation of the Education and Training Voucher program (ETV). The guidance requires States to submit an application amending and expanding the base CFCIP plan, specifically the educational assistance component. This application requires States to describe how they will implement the new voucher program and its required conditions, including strengthening the educational activities already in place.

States are also being encouraged to coordinate their program with other appropriate education, training and dropout prevention programs. These programs include, but are not limited to, the Department of Education's Upward Bound program, the Department of Labor's Workforce Investment Programs for out-of-school youth, and private sector initiatives such the Orphan Foundation of America's Scholarship program and the Community College Foundation's Peer Counseling program in California.

Another way we hope to ensure efficiency is by encouraging States to work with the student financial offices of educational and training institutions to certify an individual's eligibility for the voucher program. In the guidance, we specifically reference the Free Application for Student Financial Assistance (FASFA) as a resource to assist jurisdictions in certifying eligibility for the ETV program. States are encouraged to use the FASFA as it may be a helpful tool for identifying youth eligible for the ETV program as a part of the case planning activities specifically related to preparation for post secondary education and training; and as a method for certifying the youth's financial status.

QUESTION SUBMITTED BY SENATOR ERNEST F. HOLLINGS

STROKE

Question. Mr. Secretary, I would like to spend a minute discussing your agency's stroke-related activities. As you know, stroke is the third leading cause of death in United States and a major cause of permanent disability. My home state of South Carolina falls within the group of Southeastern states known as the "Stroke Belt" where stroke death rates are significantly higher than the national average. More than half of my state falls within the "Stroke Buckle," a part of the "Stroke Belt" where stroke death rates are twice the national average. South Carolina is at the epicenter of an epidemic. We have the highest stroke death rate in the nation and have held that unfortunate distinction for the past five decades.

I noted with great interest the recent release of the CDC's the "Atlas of Stroke Mortality: Racial, Ethnic, and Geographic Disparities in the United States." The document does a great job defining the extent of the problem but does not prescribe a solution to the. problem. For that we need a larger portfolio at the NIH. I am concerned given the significant impact that stroke has on the lives of so many citizens, the NIH invests only 1 percent of its budget on stroke research. At the encouragement of this Subcommittee, the National Institute of Neurological Disorders and Stroke's Stroke Progress Review Group identified critical gaps in stroke knowledge and outlined 5 research priorities and 7 resource priorities. Mr. Secretary, what can you tell us about your plans to implement these recommendations? I would also appreciate hearing any additional plans you may have to alleviate and prevent stroke in the "Stroke Belt" and the "Stroke Buckle?"

Answer. NIH continues to place a high priority on stroke-related research. The stroke program of the National Institute of Neurological Disorders and Stroke (NINDS) ranges from basic investigation of stroke mechanisms through large studies of risk factors and clinical trials aimed at prevention or treatment. Interventions under investigation besides the "clot-buster," t-PA, include drugs, surgery, vitamins, physical therapy, and psychosocial modalities. Research is also targeted to special issues of stroke in minority populations, women, and children, and in geographic regions such as the "stroke belt."

The NINDS has formed a Stroke Working Group (SWG) of Institute Program Directors who work on stroke to implement the recommendations of the Stroke Progress Review Group (SPRG). This group matched current NINDS stroke activities to SPRG goals, including basic genetic studies, research to understand the process of stroke recovery, development of better animal models of stroke, expansion of stroke imaging research, and development of new designs and methods for stroke clinical trials. The NINDS Stroke Working Group continues to meet regularly to re-

view progress in implementing the recommendations of the SPRG, and to discuss plans for future activities.

The NINDS already supports, or is planing, a variety of stroke center programs that address a number of SPRG recommendations. A new initiative, Specialized Program of Translational Research in Acute Stroke ("SPOTRIAS") will facilitate translation of basic research findings into clinical practice, in settings where patients are evaluated and treated very rapidly after the onset of their symptoms. The intent of the SPOTRIAS is to support a collaboration of clinical researchers from different specialties whose collective efforts will lead to new approaches to early diagnosis and treatment of acute stroke patients. Training and career development will be part of the SPOTRIAS program.

Other ongoing efforts are focusing on expanding education and training of stroke medical and research personnel, a resource priority identified by the SPRG. Initiatives in this area include the Mentored Clinical Scientist Development Award, Mentored Patient-Oriented Research Career Development Award, NINDS Career Transition Award, and the Mid-Career Investigator Award in Patient-Oriented Research.

We know the "Stroke Belt" is an area in the Southeastern United States with stroke mortality rates approximately 25 percent above the rest of the nation, and contains a region of even higher stroke mortality (the "Stroke Buckle"). African American stroke mortality is 50 percent higher than in whites. The NINDS has initiated several studies to address this phenomena. The NINDS, NHLBI and NCRR are jointly supporting a Stroke Prevention/Intervention Research Program at Morehouse School of Medicine in Atlanta. The goals are to further understand the etiology of stroke among rural and urban African Americans who reside in the Stroke Belt. Based on the data obtained, community-specific stroke prevention and intervention projects will be crafted and evaluated. Additionally, the Institute supports a study, "Etiology of Geographic and Racial Differences in Stroke" in Alabama. The role of geographic and racial differences in incidence as contributors to the differences in mortality rates will be examined and risk factors estimated. Also, the role of candidate genes for stroke will be investigated. This study addresses the wide range of hypothesized causes of the excess stroke mortality in the Southeastern US and among African Americans, and will provide information to design interventions to reduce the excess stroke mortality in these populations.

QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

MEDICARE PLUS CHOICE

Question. As I hear all this rhetoric about injecting competition and choice into Medicare to save the program, I must ask myself, where's the competition and choice in my State? There are only two Medicare HMOs in the whole State of West Virginia, and they enroll less than two percent of the entire State's Medicare population. The seniors in my State depend on a strong and viable traditional, fee-for-service Medicare program. "Choice" seems to be a favorite theme of this Administration. In the Medicare program, right now, seniors have the choice of their individual doctor. That's what most people in West Virginia think about when they think about choice. The last thing seniors in my State need is a forced choice between the family doctor they know and trust and the prescriptions drugs they need to live. Mr. Secretary, what happens under the Administration's current deregulation scheme, to the poorest and sickest seniors in West Virginia who are left in a Fee-For-Service Medicare plan, without drug coverage, facing skyrocketing premiums, and with no HMOs or private health plans coming to their rescue?

Answer. Senator, President Bush is not about to let that happen, and the Framework to Modernize and Improve Medicare takes steps to ensure that all Medicare beneficiaries have access to an Enhanced Medicare plan with meaningful prescription drug coverage.

Enhanced Medicare will be a system of PPO-style plans that will be awarded contracts to serve entire multi-state regions. Under those contracts, the PPOs will be required to take all beneficiaries—those in the cities, as well as those in the rural areas. This structure will be fundamentally different than the county-by-county contracts you are familiar with in Medicare+Choice. This system of regional contracting has worked successfully for TRICARE in the military health system. That's why we believe that the regional PPO approach is right for Medicare.

PPOs have been a growing form of health insurance and are now the most popular type of coverage in the private market. Among individuals with employer group coverage, 52 percent are enrollees of PPOs as of 2002. Today's workers will age into

Medicare with experience with PPO coverage. Indeed, 78 percent of large employers offer a PPO option to pre-65 retirees.

So all Medicare beneficiaries will have the option of Traditional Medicare or Enhanced Medicare as described above. In addition, for those who choose to stay in Traditional Medicare, the Framework protects them from undue premium increases. Part B premiums would continue to be calculated as though current law were in effect.

MEDICARE PRESCRIPTION DRUG PROPOSAL

Question. Mr. Secretary, you have repeatedly stated that the Administration's proposal to reform Medicare is modeled after the Federal Employees Health Benefit Plan (FEHBP), which offers several different health plans for Federal employees. However, in States like West Virginia, comparing Federal employees participating in the FEHBP to Medicare beneficiaries participating in the Medicare program is like comparing "apples and oranges." The Federal employees in West Virginia are much younger, wealthier, and healthier than the Medicare beneficiaries in West Virginia. Medicare beneficiaries in West Virginia are either elderly or disabled, and tend to be heavy utilizers of costly health care services. Further, the health plans offered to Federal employees in West Virginia through the FEHBP are all concentrated in only small pockets of my State, the Northern and Eastern Panhandle regions, which are less rural. There are very few Federal health plans offered in southern West Virginia. Mr. Secretary, can you offer an explanation as to how a Medicare prescription drug proposal, modeled after the Federal Employees Health Benefit Plan, would work in West Virginia?

Answer. The difference, Senator, is in how Enhanced Medicare defines its service areas. Under Enhanced Medicare, beneficiaries could choose to receive integrated benefits and drug coverage offered through a FFS/PPO plan, like FEHBP or TRICARE. The plans would bid to serve one or more of 10 multi-state regions, and by doing so they would agree to serve the entire region, cities and rural areas alike. In addition, all beneficiaries in a region are guaranteed access to any of the three plans that are entrusted to serve the region. Beneficiaries who enroll in an average-priced plan in their region would pay a premium equal to the Part B premium in traditional Medicare. Those choosing the plan with the low-priced bid would receive most of the savings, while those choosing the high-priced bid would pay a supplemental premium. Beneficiaries would pay an additional premium for drug coverage, except for those with low incomes. New benefits in the enhanced package include a combined deductible for Part A & B services, free preventive benefits, and protection from high out-of-pocket medical costs.

In designing the framework, the President is looking toward other federal programs that have successfully brought coverage to federal workers in big city offices, to forest rangers in remote areas, and all federal workers and their dependents in between.

PRESCRIPTION DRUG COST

Question. Mr. Secretary, according to an article in The Wall Street Journal on February 24, 2003, it appears that taxpayers as well as Medicaid are being significantly overcharged for prescription medications by certain pharmaceutical companies. The article states that "despite a 1990 law requiring drug makers to report to Medicaid the lowest prices they charge anyone, some big pharmaceutical companies simply aren't doing so." The result is taxpayers and Medicaid are paying more than their fair share for prescription drugs. Mr. Secretary, I find this matter deeply troubling and wonder why the Administration has chosen to ignore this glaring loophole in the law in its current Medicaid proposal?

Answer. This administration has by no means ignored the complications surrounding prescription drug pricing. In fact, the President's budget proposes to work to work with congress to improve the Medicaid drug rebate system. There are many means by which we can generate program savings. We look forward to working with you to determine the course of action that will best address the concerns of the American taxpayer.

MEDICAID PROPOSAL

Question. Mr. Secretary, I am concerned that the Administration may be trying to take advantage of the current fiscal crisis facing States in order to sneak out of the Federal government's financial obligations to the poor and disabled and to cap what is now a guarantee of specific health benefits. The Administration's Medicaid proposal would essentially eliminate the federal guarantee of certain health benefits for a significant portion of the Medicaid population. Why is the Administration dis-

mantling this health care safety net at a time when many Americans are vulnerable from the struggling economy and rising health care costs?

Answer. The Administration has proposed State Health Care Partnership Allotments to deal directly with the problems of coverage being eliminated due to constrained State budgets. States can currently eliminate coverage for non-mandatory populations and many states have already made cuts. We are not eliminating any guarantees that currently exist.

The Medicaid reform package gives States alternatives to merely cutting the rolls. Instead of solving budgetary dilemmas by cutting whole populations, the allotment model would allow States to strategically construct services in ways that most ably address the specific needs of their unique Medicaid and SCHIP populations.

Once again let me stress, mandatory services for mandatory populations will not be affected by the reform package. We are not allowing States to cut any populations they can't already cut through State Plan Amendments. We hope that we have given States a more humane alternative to eliminating benefits for needy Americans.

SCIENTIFIC ADVISORY COMMITTEE

Question. Mr. Secretary, I found it extremely disturbing to read on the front page of The Washington Post last Fall that the Bush Administration has been quietly overhauling the 250 scientific advisory committees that guide the Department of Health and Human Services (HHS) on a wide range of health issues. I am concerned that the Presidents message to scientific advisory committees within his Administration reads: either you're with us or you're against us. While the Administration talks about supporting programs that are shown by science to be effective, at the same time, the Administration is reshuffling the independent panels and stacking them with handpicked, partisan choices. Mr. Secretary, why should the general public have any confidence in the recommendations of these advisory panels when their independence and objectivity appear to have been compromised?

Answer. There are over 250 Secretarial Advisory Committees at the Department of Health and Human Services. By Congressional charge the Office of the Secretary is responsible for making appointments to these committees. Vacancies on these committees occur regularly for a variety of reasons including resignations and expiring terms. We are also charged with maintaining the charters of these committees and from time to time we must update charters as they also expire. As a result, we will make hundred of appointments in the course of any year and update several charters in the same time frame.

Let me assure you that this Department fully supports and understands the need to select members for scientific advisory committees who are the best suited to promote health in our nation. Under the General Services Administration manual's chapter on Advisory Committee Management, we are required to adhere to certain policies. For example, we must ensure that the nomination, selection, and appointment process results in selections that are balanced in terms of views represented. I am confident that we have in place procedures to ensure that we select members who are not only experts, but whom we believe will provide objective assessments on important scientific matters without prejudice or prejudgment.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you all very much. The subcommittee will stand in recess to reconvene at 9:30 a.m., Thursday, March 27, in room SD–192. At that time we will hear testimony from the Honorable Roderick Paige, Secretary, Department of Education.

[Whereupon, at 10:27 a.m., Wednesday, March 19, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, March 27.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2004

THURSDAY, MARCH 27, 2003

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:04 a.m., in room SD–138, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Stevens, Harkin, Murray, and Landrieu.

DEPARTMENT OF EDUCATION

OFFICE OF THE SECRETARY

STATEMENT OF HON. RODERICK PAIGE, SECRETARY OF EDUCATION

ACCOMPANIED BY WILLIAM HANSEN, DEPUTY SECRETARY OF EDUCATION

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The Appropriations Subcommittee on Labor, Health, Human Services, and Education will now proceed.

This morning we will hear from the distinguished Secretary of Education, the Honorable Rod Paige, who will present the administration's budget, which is $53.1 billion, an increase of $26 million over the fiscal year 2003 program level. That is an increase, obviously, of a minor proportion, less than the inflation rate.

PROGRAM REDUCTIONS AND ELIMINATIONS

As we take a look at some of the programs which are being cut or eliminated, they pose some real issues for the subcommittee—the reduction in GEAR UP, the Rural Education program cut by $167 million, which would, I am told, eliminate the program; a significant cut of $326 million for vocational education programs; and a problem which confronts this subcommittee is that the budget for education is joined in our overall allocation with health and also labor worker safety, which gives us a lot of very hard choices.

We have advanced the time of this hearing to 9 o'clock, so that we could be available to meet with the full committee, which is

going to hear testimony from the Secretary of Defense and the Secretary of Homeland Security at 10:00.

And I will yield now to the chairman of the full committee, Senator Stevens, with your permission, Senator Harkin.

OPENING STATEMENT OF SENATOR TED STEVENS

Senator STEVENS. Well, thank you, because I do have to organize that other hearing with both the Homeland Security and Defense. I do have a long statement. I would like to have it put in the record.

Senator SPECTER. Without objection.

ALASKA'S REQUEST FOR FLEXIBILITY

Senator STEVENS. I would like to personally ask the Secretary about the problem of responding to Alaska's request with regard to flexibility. We have had both the letter that was written to you last June and then the meeting with our Governor Frank Murkowski about the problem that we have of so many small schools in areas where, in many cases, we are unable to get teachers, let alone teachers' assistants; and we have not received any indication that there is going to be any flexibility in dealing with those issues.

RURAL EDUCATION IN ALASKA

I urge you to read my statement. I do not want to hold up the committee. But Alaska's native population is 25 percent of the enrollment of our schools. The bulk of it is in these small areas, very small areas, small villages. And it is just impossible for us to follow the bill we support, which is that no child should be left behind, from the point of view of getting the people that are necessary to carry it out. If we cannot hire teachers, how can we hire teachers' assistants and people, special people, to qualify those who are not keeping up? And in many cases, it is a cultural language problem, where the parents refuse to allow the children to study in English.

We do not have BIA schools. And yet we find that your budget has reduced the funding for the two basic programs, the Education Equity Act from $31 million to $14 million, and the Alaskan-Native Hawaiian Institution Program from $8.2 million to $4 million. And you also reduced the funding for the Carol White Physical Education Program from its current level to $10 million. It was $60 million. That meant you put $10 million in another program that is not really authorized by Congress.

Now, Mr. Secretary, some of us have taken on a lot of responsibility around here trying to help run the Senate. And I do not think that means we deserve any extra consideration, but it means we should be treated as a State and as representing a State in a way that we can get answers. I would again ask you to come up and take a look at the villages and see the problems. I do not think your people—your people came up, and they did not leave the main cities. They did not go to the villages. And our problems are in the villages. Even our small Barrow College, the college that is there for native children, your people ignored it entirely.

PREPARED STATEMENT

So I hope that by the time this markup comes, Mr. Chairman, I am going to ask you to put some severe restrictions on the Department of Education with regard to the use of funds unless they pay attention to the rural areas that cannot comply with this law.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TED STEVENS

Thank you Mr. Chairman, and I'm pleased to welcome Secretary Paige to our subcommittee.

Mr. Secretary, I thank you for the leadership you are demonstrating in working to ensure that no child in America is left behind in getting an education that will prepare him or her to lead a productive life in the 21st century.

Yours is not an easy task, especially in times like these when our ability to provide funding for these programs is severely challenged by the needs of homeland security and supporting our defense needs.

I do have some concerns about how your Department is responding to our State of Alaska's need for flexibility in meeting the standards of the "No Child Left Behind Act."

Last June, Alaska's education commissioner sent you a letter requesting flexibility for our State in meeting timelines for qualifications of teachers and teacher aides, and testing in english of students at early ages.

To the best of my knowledge, the department has yet to receive a written response from the Department to its request.

In January, Alaska's Governor, Frank Murkowski, met personally with you and your senior staff to discuss the issues raised in the June 2002 letter.

I understand that the Department has taken the position that it will not grant any waivers for the "No Child Left Behind Act" requirements.

I also understand that when the Department sent up a team to alaska to "peer review" its proposed State plan, that the team did not choose to accept the State's invitation to visit remote rural communities to see just how different conditions in my State are from those in the South 48.

Alaska has 54 school districts, with the largest 5 enrolling 70 percent of students. Thirty-nine school districts in my State each enroll less than 1 percent of the student body.

My State has a large number of very small schools, each with only a handful of teachers. Of 506 schools, 135 schools have fewer than 50 students and 82 enroll 25 or fewer students.

Many of these schools are located in villages not served by roads, where the only means of transport among villages is via plane or dog sled.

I am concerned about what my State perceives as a lack of responsiveness by your Department to these issues.

Last year I invited you to come to Alaska and see these conditions for yourself. Once again, I extend the same invitation.

I also ask that within the next 30 to 60 days you send appropriate members of your staff to my State to visit representative schools in rural Alaska and to work with Governor Murkowski's administration to arrive at an equitable solution to these issues.

I'm also disturbed about several decreases and program eliminations in your budget proposal.

Alaska's Native population is almost 25 percent of total enrollment in our schools. Our State has assumed the responsibility for educating all of its students, and we do not receive any Indian education funding, nor do we have BIA schools.

Alaska's Native children need the resources provided under the Alaska Native Education Equity Act to provide the extra help many of them need to succeed in school.

Yet, for the second year in a row, your Department is proposing to cut this funding to $14 million from its present fiscal year 2003 level of $31 million.

In the higher education area, your budget proposes to cut funding for the Alaska Native—Native Hawaiian Serving Institutions program from its present level of $8.234 million to only $4 million.

You have eliminated entirely funding for the Echo Act, which provides funding for cultural enrichment and job training activities for our Alaska Native Heritage Center and our Inupiat Heritage Center.

All of these programs are authorized in law.

Mr. Secretary, I would like to have you share with this subcommittee why your Department persists in slashing funding and even eliminating programs which are desperately needed by my State's Native people.

On another topic, the Department has also zeroed out funding for the "Carol M. White Physical Education for Progress" program—also authorized in law—from its current level of $60 million.

I am particularly disturbed by this, because you and the administration have publicly voiced support for physical education programs as a means of combating our epidemic of obesity among America's children, and your budget proposes a similar initiative to be funded at $10 million.

Mr. Secretary—what's wrong with my pep program—one that is supported by most of the advocacy groups supporting increased emphasis on physical fitness for kids?

Mr. Secretary, I'm also concerned over significant cuts to the Impact Aid program, which is of great benefit to many schools in Alaska, and I hope your staff will work with our subcommittee to restore this important source of support to federally-impacted school districts.

I look forward to your testimony Mr. Secretary and to your visiting Alaska in the near future.

Senator SPECTER. Thank you, Senator Stevens.

Senator Harkin.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you, Mr. Chairman. I will try to be brief. I would also ask that my full statement be made part of the record.

FISCAL YEAR 2004 BUDGET REDUCTIONS

I just want to associate myself with the statements of our chairman, Senator Specter, in his opening remarks. The President's budget would increase Education Department funding by $26 million or .05 percent. It does not help schools meet the requirements of No Child Left Behind.

In Iowa, it is estimated 56 percent of all the schools will be designated next year as needing improvement under the No Child Left Behind law. It will go up even higher in years after that. But this budget cuts funding for the No Child Left Behind programs by $1.2 billion from this year's level.

Now I noticed in your opening statement, you point out that the President's budget represents more than a 25 percent increase since 2001. Well, thanks to Congress. In spite of the President's budget, we increased it that much. The President's budget did not. We did here in the Congress on a bipartisan basis. I just think that the cuts that are made in the budget request from this year's level are really unconscionable.

The $400 million cut for 21st Century Community Learning Centers would mean no more after-school services for 550,000 children. Surely the administration does not think kids will be better off alone or home alone or out on the streets than in after-school programs in school-based settings.

RURAL EDUCATION PROGRAM CUT

I also want to again repeat for emphasis' sake what the chairman said. The $167 million cut in the Rural Education program is really not acceptable. That zeroes out the whole rural education fund program that we had specifically outlined. It is important to my State of Iowa. It has never been a partisan program, Repub-

lican or Democrat. It was authorized in No Child Left Behind. It has broad support here. And yet the administration wants to zero it out.

PREPARED STATEMENT

Mr. Secretary, again, I just repeat: This budget is totally inadequate. And it is leaving us in a heck of a situation here to try to correct it and get the education funding back up. Again, as you know, I have personally a high regard for you and respect for you. But this budget from the administration is just unacceptable.

Thank you, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TOM HARKIN

Mr. Secretary, thank you for joining us today for this hearing. I believe this is your third appearance before this subcommittee.

We've had some vigorous debates in the past, and maybe we'll have another one today.

Unfortunately, once again I am disappointed in the President's proposed budget for education. Overall, it would increase Education Department funding by just $26 million. That's just 0.05 percent—it doesn't even cover inflation.

The President's budget is far from adequate to help schools meet the requirements of the No Child Left Behind Act.

In Iowa, many parents and educators are just now coming to grips with the fact that next year, an estimated 56 percent of all the schools in the state will be designated as "needing improvement" under this new law. The numbers will go up even higher in the years after that.

But what does this budget do? It cuts funding for No Child Left Behind programs by $1.2 billion from this year's level. That is unconscionable.

I am particularly disturbed by the proposed $400 million cut for 21st Century Community Learning Centers. This cut would mean no more afterschool services for 550,000 children. Does this administration really think that children will be better off at home alone or out on the streets than in a school-based, afterschool program?

But beyond the question of funding, I'm frustrated by the Administration's disregard for Congressional priorities when it comes to programs like rural education, dropout prevention, and dozens of others that the President plans to eliminate.

Take the rural education program, which is particularly important for my state of Iowa. This is not a Democratic program or a Republican program. It is a bipartisan program authorized in the No Child Left Behind Act. It has broad and strong support in Congress. It helps a group of students that are particularly at risk of being left behind.

Members from both parties understand this. And yet the Administration wants to zero it out.

Mr. Secretary, you know I have a great deal of respect for you personally. I know you want all children to succeed. But this budget will not do the job. I assure you that I and others on this subcommittee will do everything we can to increase funding for education in the months ahead.

I look forward to hearing your statement and discussing this more in the question-and-answer period.

Senator SPECTER. Senator Murray, would you care to make an opening comment?

OPENING STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Mr. Chairman, I know we have a short amount of time, and we want to hear from the Secretary and have a opportunity to ask our questions. So I will submit my statement for the record.

BUDGET CUTS AND NO CHILD LEFT BEHIND ACCOUNTABILITY

But I want to associate myself with the remarks made by both the chairman and the ranking member. I find the President's budget to have serious shortfalls. And I think all of us who have been home are hearing screaming and yelling from our States. Everyone wants to meet the accountability requirements of No Child Left Behind, but at this point they really believe this is an unfunded mandate that has been passed down to them because we have not followed through with the resources.

PREPARED STATEMENT

I agree that zeroing out funding for impact aid and rural education reductions in everything from after-school programs to safe and drug-free schools, not meeting the commitments of Title I, all of it just puts our schools at a serious disadvantage in trying to meet the accountability requirements they really want to meet. They want to work with us to do that. So I am very disconcerted by the President's budget. And I have some questions, and I will ask them during the round.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF SENATOR PATTY MURRAY

Thank you Mr. Chairman for giving us this opportunity to discuss the Administration's fiscal year 2004 budget with Secretary Paige. And thank you Secretary Paige for being here today.

I'd like to remind everyone of the context in which we sit here today. The Administration has sent us a budget that proposes a $1.2 billion cut in funding for the No Child Left Behind Act, while funding a $1.4 trillion tax cut. This budget request—with its meager investment in funding for the No Child Left Behind Act—fails our children and fails their future. It fails the very promise that the President made to students when he signed the No Child Left Behind Act just two years ago.

Leaving no child behind is a noble goal, and with bipartisan support, we passed an education reform bill to meet that goal. But this budget does not come close to meeting the needs of our students or keeping the promises of that legislation. When we passed the No Child Left Behind Act, we passed it based on two commitments. First, we would hold schools accountable for their progress, and second, we would provide schools with the resources to meet those new requirements.

We're certainly keeping the first part of that bargain. But this budget suggests that the Administration does not intend to keep the second part of their promise. Why is this Administration willing to keep the commitment to identify schools in need of improvement, but unwilling to keep the commitment to provide the resources for those schools to improve?

Let me highlight a few of the ways this budget shortchanges America's students. This budget could cut funds for after school programs for more than 500,000 latch key children. That's on top of the more than 6 million latch key children we're already not serving. It leaves 6 million of our most disadvantaged students behind by not providing the Title I funding they need. Among other things, it also falls short on funding for teacher quality and class size reduction, for English language acquisition, for Impact Aid for Safe and Drug Free Schools, and for rural education.

At a time when we are demanding more than ever from our students, teachers and schools, this budget does not invest more in them. At the Department of Education you are no doubt getting a bird's eye view of how hard our states are struggling to implement this law. Everywhere I go in my home state of Washington I hear from educators who believe in the goals of the No Child Left Behind Act. They're willing to work as hard as they have to do to make it work. But they can't do that without resources. That's why the bill promised significant increases in resources.

Leaving no child behind means making serious investments in things like Title, IDEA, smaller classes, teacher quality and after school programs. These are the

type of real reforms that will make a difference for our students, and these are the reforms that are underfunded or cut in President Bush's proposal.

Senator SPECTER. Senator Landrieu, would you care to make an opening statement?

OPENING STATEMENT OF SENATOR MARY LANDRIEU

Senator LANDRIEU. Yes, I do. Thank you.
And welcome, Mr. Secretary.
Secretary PAIGE. Thank you.

BUDGET REDUCTIONS AND NO CHILD LEFT BEHIND

Senator LANDRIEU. I look forward to continuing to work with you as we fashion a stronger accountability program for our Nation's schools. But just a note: I associate myself with the remarks previously made. I want to go on record as saying that the President's budget is wholly inadequate to support the commitment that he made personally to the schools in Louisiana and to the schools throughout our Nation. He reneged, in my opinion, on his promise to fund the Leave No Child Behind Act.

I think it is the height of hypocrisy for him to open his budget with the quote "The time for excuse-making has come to an end." The President himself continues to make excuses to this Congress about why he cannot find the money to meet the commitment that he made specifically to Title I and to Special Education.

There was no, to my knowledge, misunderstanding in these negotiations. I was in the room when the negotiations were made. It was very, very clear in the negotiations made on Leave No Child Behind that Congress would adopt the testing requirements and the President would step forward with the funding. Well, he reneged on this promise. He continues to make excuses and I think it is a shame.

LOUISIANA ACCOUNTABILITY SYSTEM

Second, I want to say that there are five States in this Union, Louisiana being one of them, that have an extraordinary accountability system that was in place long before the one that we designed went into effect. My superintendents and my principals have been operating this system with extremely good results. I am told the current Federal law is in some ways in conflict with their efforts.

Louisiana is not asking, Mr. Chairman, for lower standards, we are asking for using common sense. I know the Secretary is aware of Louisiana's situation and I would like you to personally examine our unique situation and try to respond as soon as possible.

[TThe information follows:]

LOUISIANA STATE ACCOUNTABILITY PLAN UNDER NO CHILD LEFT BEHIND

Louisiana's plan for an accountability system, which both builds upon the State's existing accountability system and responds to the No Child Left Behind (NCLB) Act requirements, has been approved by the U.S. Department of Education. Louisiana is the 11th State to gain approval of its State accountability plan.

Included below is the April 17, 2003 U.S. Department of Education Press Release announcing the approval of Louisiana's plan. Information on the No Child Left Behind Act may be found at the No Child Left Behind website: /http://www.nclb.gov/ . A copy of the Louisiana State Accountability Plan, along with other approved State

plans, may be found at the Ed website: http://www.ed.gov/offices/OESE/CFP/csas/index.html.

PAIGE APPROVES LOUISIANA STATE ACCOUNTABILITY PLAN UNDER NO CHILD LEFT BEHIND

BATON ROUGE, LA.—Louisiana has completed work on a plan for a strong state accountability system aligned with the No Child Left Behind Act (NCLB) of 2001, U.S. Secretary of Education Rod Paige announced today.

Paige made the announcement today during a visit to the state capitol where he was joined by Governor Mike Foster and State Superintendent Cecil Picard.

"Louisiana has built upon its existing state accountability system to produce an even stronger and more cohesive plan to benefit every child in the state," said Paige. "I congratulate Superintendent Picard and Governor Foster for this step forward. Louisiana has a distinguished history of education reform and cutting-edge work in assessment and accountability. With these improved accountability provisions and an established record of reform, Louisiana is firmly on the path to ensuring that no child is left behind."

Under NCLB's strong accountability provisions, states must describe how they will close the achievement gap and make sure all students, including disadvantaged students, achieve academic proficiency. In addition, they must produce annual state and school district report cards that inform parents and communities about state and school progress. Schools that do not make progress must provide supplemental services such as free tutoring or after-school assistance, take corrective actions and—if still not making adequate yearly progress after five years—must make dramatic changes in the way they operate.

Louisiana is the 11th state to gain approval. Other states whose plans have been approved include Colorado, Delaware, Indiana, Kansas, Maryland, Massachusetts, Mississippi, New York, Ohio and West Virginia.

No Child Left Behind is the landmark education reform law designed to change the culture of America's schools by closing the achievement gap, offering more flexibility, giving parents more options and teaching students, based on what works. Foremost among the four key principles is an insistence on stronger accountability for results. To achieve that, states must develop strong accountability systems or improve those already in place, establish high standards and hold all children to the same standards. They also must provide instruction by highly qualified teachers that results in steady progress and, ultimately, proficiency for all students by the 2013–14 school year.

Secretary Paige recently asserted that the new law aims to correct the "previous and pervasive separate and unequal education systems that taught only some students well while the rest—mostly poor and mostly minority—floundered or flunked out."

All states submitted draft accountability plans to the U.S. Department of Education by the Jan. 31 deadline. Following an initial review and technical assistance, if needed, the next step is on-site peer review of each state's proposed accountability plan. Teams of three peer reviewers—independent, nonfederal education policy, reform or statistical experts—conduct each peer review. Following a review of the team's consensus report, the department provides feedback to the state and works to resolve any outstanding issues. Ultimately, Paige approves the state plan, as he did today.

To date, 47 states and the District of Columbia and Puerto Rico have had peer reviews of their accountability plans. Additionally, the senior staff of the Department of Education has finished meeting with education officials from the states to discuss the specifics of their plans and the unique challenges and issues in each state.

Despite all the priorities competing for our tax dollars, President Bush's budget boosts federal education funding to $53.1 billion—an $11 billion increase since the president took office. Louisiana alone will receive more than $914 million, including $385 million to implement NCLB. If the president's budget is approved, federal education funding for Louisiana will have gone up $166 million since he took office.

Louisiana's plan will be posted online in the coming days at: http://www.ed.gov/offices/OESE/CFP/csas/index.html.

For more information about the No Child Left Behind Act, go to www.nochildleftbehind.gov.

STATE ACCOUNTABILITY PLANS UNDER NCLB

Senator SPECTER. Senator Landrieu, could you conclude your opening statement?

Senator LANDRIEU. Yes, I will.

The reason, Mr. Chairman, I raise this is because this trend could be quite discouraging to the other States. If the five States that are moving forward so aggressively are discouraged from their efforts, then I fear that all the other States will be discouraged and we will be defeating our purpose.

PREPARED STATEMENT

I would end my remarks by saying: The time for excuses is over. The President and his administration should be the ones that stop making excuses and be a good example for everyone else.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF SENATOR MARY LANDRIEU

Thank you, Mr. Chairman. Mr. Secretary, thank you for being here this morning. As evidenced by my work in passing the No Child Left Behind Act, I believe wholeheartedly in this law's founding principles: accountability for results, flexibility and local control and the targeting of resources to the school districts, who because of a lack of local revenues, are most in need of federal assistance. The State of Louisiana is proud to be a leader in the effort to hold schools and districts accountable for performance. In fact, a nationally renowned publication, Education Week, recently singled out our statewide accountability system as being amongst the best in the Nation. I remain hopeful that accommodations can be made by your department to allow this success to continue.

I would like to begin my comments here this morning with a quote from the speech that President Bush delivered on January 8, 2003, the day he signed the NCLB Act into law. He said, "the time for excuse making has come to an end." The President is right, we can no longer allow excuses to stand in the way of all of our children receiving a high quality education. The future of our National economy is dependent on our ability to replace excuses with results. But what I think may be lost in the translation, is that the time for excuse making has come to an end for us all. It is no longer appropriate for the federal government to excuse themselves from their responsibility to America's public school system.

Mr. Secretary, as you know there were a lot of things written into to law by the No Child Left Behind Act. I would like to call your attention to Section 1002 of Title I of this bill. It is here that we made the commitment to increase Title I by $2.5 billion a year for the next six years. In addition, in Section 4206, of this bill we carefully laid out the funding for the 21st Century After School program. In both cases, the amount of the increases were the result of a carefully constructed compromise between the White House and members of Congress who felt that reform and resources for reform must go hand in hand. Despite this, the President's budget only calls for an $650 million increase over last year for Title I and perhaps even more shocking, calls for a reduction of $400 million in after school. By doing this, the President, in essence, excuses himself from the requirements of these sections of the NCLB act while at the same time insisting that States, locals and schools be bound to all other requirements of this bill.

In addition, the President insisted that all new programs, particularly in reading, be research based programs and then excuses himself from the federal commitment made to provide the funding to promote this research and best practices through programs such as the Comprehensive Regional Assistance Centers and the Eisenhower Regional Math and Science Consortia. In my state of Louisiana, these programs are crucial to our ability to translate research into effective practice. The rationale behind these cuts, I am told, is that States are allowed to use their limited Title I dollars to fund research and best practices at the local level and it is the view of this Administration that the states are better suited than Universities and Regional Academic Consortia to engage in this practice. Not only does this policy add to the burden on states to choose between the many needs of limited Title I

funds but it also wrongly assumes that states are better equipped to perform this function.

The most disturbing excuse of all, however, is that these smaller than promised increases and cuts are the consequence of a deficit budget and the costs of the war. True, these efforts will require the majority of our attention and resources. Yet, while the President is saying that his recommended increase are all our current fiscal status will allow he is at the same time able to find the resources to fund $100 million mentoring program, $75 million school choice demonstration program and a $2,500 tuition tax credit for children who transfer to a higher performing schools. While each of these programs may be worthwhile, I can't help but wonder if it is appropriate for us to be spending our precious resources to give a few students the option to attend a better school instead of funding the reform necessary to give all students the opportunity to succeed.

Mr. Secretary, there are a lot of good things in this budget, but there are also a lot of excuses. I hope that we can work together to make the targeted investments necessary to provide the high quality education our children need and deserve.

Senator SPECTER. It is not customary to have anybody but the chairman and ranking make an opening statement. But in view of the limited number of people here, I try to extend the courtesy. But they have to be brief in the context where we are having another hearing at 10 o'clock.

Mr. Secretary, the floor is yours.

SUMMARY STATEMENT OF HON. RODERICK PAIGE

Secretary PAIGE. I will be very brief, Mr. Chairman. And thank you so much for this opportunity to come. Ladies and gentlemen, thank you. I have just a brief statement here.

In total, the President's budget demonstrates his ongoing substantial commitment to supporting educational excellence and achievement. More importantly, it reaffirms that the Federal support for education is about more than money. It is about reform through high standards and through leadership and through the use of proven education methods. Only through the combination of these resources, with effective leadership exemplified in the President's No Child Left Behind initiative, can America's children and adults benefit.

PREPARED STATEMENT

I will end this by asking that you recognize that the President's 2004 budget request is somewhat unusual in that it was developed before the Congress completed its work on the 2003 appropriations. The request for the Department of Education reflects the administration's relative priorities at that time within the overall 2004 discretionary totals. We are prepared to work with the Congress to adjust some of these priorities in light of the 2003 appropriations, as long as the overall discretionary appropriations do not exceed the total of the President's budget.

Mr. Chairman, with that abbreviated statement in vieu of the time, I end my statement.

[The statement follows:]

PREPARED STATEMENT OF HON. RODERICK PAIGE

Mr. Chairman and Members of the Committee: Thank you for this opportunity to testify on behalf of President Bush's 2004 Budget for the Department of Education. I am proud to appear before you today, discussing the many ways that President Bush's 2004 Budget and other initiatives support educational opportunity for American children and adults.

As you know, earlier this year we celebrated the first anniversary of the No Child Left Behind Act of 2001, which President Bush signed into law on January 8, 2002. State officials, administrators, and teachers across the country now are working hard to strengthen their accountability systems, identify research-based strategies for improving student achievement, and offer new choices to parents whose children attend low-performing schools.

The President's budget seeks $53.1 billion for Department of Education programs in 2004. That represents more than a 25 percent increase since 2001, and a 130 percent increase in Federal education funding since fiscal year 1996. Key requests for the cornerstones of the Federal role in education include:

—$12.4 billion for Title I, a 41 percent increase since the passage of No Child Left Behind;

—$9.5 billion for IDEA grants to States, a 50 percent increase since he was elected President; and

—$12.7 billion for Pell grants, for a record 4.9 million students.

In addition to discretionary spending, the President's budget provides significant mandatory support for education. The President seeks additional loan forgiveness for teachers in high-demand disciplines. He also seeks changes in the tax code to improve education. As you will recall, the President backs the CRAYOLA credit for teachers, allowing them a $400 above-the-line deduction for out-of-pocket expenses. He also continues to support the changes in last year's tax law that help students and families save for higher education.

In total, the President's budget demonstrates his ongoing, substantial commitment to supporting educational excellence and achievement. More importantly, it reaffirms that Federal support for education is about more than money. It is about reform through high standards, leadership, and the use of proven educational methods. Only through the combination of these resources with the effective leadership exemplified in the President's No Child Left Behind initiative can American children and adults benefit.

Before I go into more detail about specific areas of our request, I want to recognize that the President's 2004 Budget request is somewhat unusual, in that it was developed before the Congress completed its work on the 2003 appropriation. The request for the Department of Education reflected the Administration's relative priorities—at the time—within the overall 2004 discretionary total. We are prepared to work with the Congress to adjust some of these priorities, in light of the 2003 appropriation, as long as overall discretionary appropriations do not exceed the total in the President's budget.

IMPLEMENTING NO CHILD LEFT BEHIND

As President Bush said on the first anniversary of No Child Left Behind, "We can say that the work of reform is well begun." The Department of Education has approved the accountability plans of five States, and all remaining States submitted their plans on schedule at the end of January. We will be working with these States over the next few months to refine and complete those plans, and I am confident that all States will be on board when the new school year begins next fall. Now that the fiscal year 2003 appropriations bill has been completed and signed, the Department will be able to provide States with more reliable estimates of the Federal funding that will be available for the coming school year.

The 2004 Budget request will help ensure that this work does not falter, but continues until, in the President's words, "every public school in America is a place of high expectations and a place of achievement."

The request would provide $12.4 billion for Title I Grants to Local Educational Agencies to help States and school districts turn around low-performing schools, improve teacher quality, and increase choices for parents. This level represents a $3.6 billion increase, or 41 percent, in Title I Grants to LEAs funding since the passage of No Child Left Behind. The budget also provides $390 million for State Assessment Grants to help States develop and implement—by the 2005–2006 school year—the annual reading and math assessments in grades 3 through 8 that are integral to the strong State accountability systems required by the new law.

We are seeking $1.05 billion for Reading First State Grants and $100 million for Early Reading First, two programs that require State and local educational agencies that receive funds to capitalize on recent research findings by supporting proven methods for improving the reading skills of young children. A $185 million request for Research, Development, and Dissemination would build on this research base and fund new efforts to develop proven, research-based instruction in other subjects like mathematics.

MORE CHOICES FOR PARENTS

No Child Left Behind provides unprecedented choice for parents of children in low-performing schools. To support and enhance the law's reforms, the budget provides $75 million for a new Choice Incentive Fund to increase the capacity of State and local districts to provide parents, particularly low-income parents, more options for obtaining a quality education for students in low-performing schools; $25 million for Voluntary Public School Choice grants that would encourage States and school districts to establish or expand statewide and interdistrict public school choice programs; and $100 million to expand the new credit enhancement program that will help charter schools pay for school facilities.

IMPROVING AMERICA'S TEACHING CORPS

The President believes that well-prepared teachers are essential to ensuring that all children reach high State standards. That is why in his budget he calls for over $4.5 billion to support our Nation's teachers. Included in this total is $2.85 billion for Title II Teacher Quality State Grants; more than $500 million in loan forgiveness and teacher tax reductions; an estimated $814 million in funds supporting improvement through Title I, Educational Technology State Grants, and Title III professional development grants; $25 million for Troops to Teachers; and $190 million for the high-need areas of special education and American history.

SPECIAL EDUCATION AND VOCATIONAL REHABILITATION

President Bush has demonstrated a strong commitment to improving educational opportunities for children with disabilities, both by requesting significant annual increases for Special Education Grants to States and in his determination to apply the same rigorous accountability demanded by No Child Left Behind to the upcoming reauthorization of the Individuals with Disabilities Education Act (IDEA). Over the next year, we will be working with Congress to renew IDEA to strengthen accountability for results, simplify paperwork and increase flexibility to do what works based on sound research, and increase choice and meaningful involvement for parents.

The President also recognizes, however, that educating students with disabilities is a special challenge for States, school districts, and schools. This is why his budget would provide $9.5 billion for Special Education Grants to States, the highest level of Federal educational support ever for children with disabilities, and a $3.2 billion or 50 percent increase in Grants to States since the President took office.

The 2004 budget also supports the reform of the Federal Government's overlapping training and employment programs, first proposed in last year's budget, for individuals with physical or mental disabilities. A $2.7 billion request for Vocational Rehabilitation (VR) State Grants would help State VR agencies increase the participation of those individuals in the labor force while at the same time reduce duplication and complexity in the operation of Federal training programs.

VOCATIONAL AND ADULT EDUCATION

The Administration also will be proposing fundamental changes to vocational and adult education programs during their upcoming reauthorizations. For Vocational Education, this means greater emphasis on student outcomes and stronger links with high school programs, including activities supported by the ESEA Title I program. Our request would provide $1 billion for a new Secondary and Technical Education State Grants program that would create a coordinated high school and technical education improvement program in place of the current Vocational Education State Grants program. The new program would build on No Child Left Behind by ensuring that States and LEAs focus more intensively on improving student outcomes, such as academic achievement, and that students are being taught the necessary skills to make successful transitions from high school to college and college to the workforce.

A $584 million request for Adult Basic and Literacy Education State Grants would support reauthorization proposals that would strengthen accountability, require State standards for adult literacy activities leading to high school-level proficiency, and train teachers in the use of research-validated instructional practices.

POSTSECONDARY EDUCATION—GRANT, LOAN AND WORK-STUDY ASSISTANCE

Finally, our 2004 request would support more than $62 billion in grant, loan, and work-study assistance to an estimated 9.2 million postsecondary students and their families. The cornerstone of this assistance is a $12.7 billion request for the Pell Grant program. Since taking office, President Bush has requested an unprecedented

$4.7 billion in additional funding for this critical program. The 2004 request will enable almost 4.9 million students to receive a Pell Grant, an increase of 1 million students or 25 percent since the President took office 2 years ago.

Our postsecondary student loan programs also continue to make available needed assistance to millions of students and their families. For 2004, new student loans provided under the Federal Family Education Loans and Federal Direct Student Loans programs will grow from $44.3 billion to $47.6 billion, an increase of $3.3 billion or 7.4 percent. And these students are borrowing at the most favorable interest rates in the history of the student loan programs—just 4 percent. At the same time, student loan default rates remain low, reflecting both improved management practices and flexible repayment plans that can accommodate student needs both before and after graduation.

LOAN FORGIVENESS FOR MATH, SCIENCE AND SPECIAL EDUCATION TEACHERS IN LOW-INCOME COMMUNITIES

Also, the President is again asking Congress to approve his plan to provide additional loan forgiveness for highly qualified math, science, and special education teachers who work in low-income communities. The President's proposal will provide up to $17,500 in loan forgiveness for teachers in these three fields who work for 5 consecutive years in schools that serve high poverty student populations. This is more than three times the $5,000 in loan forgiveness now allowed for other qualified elementary and secondary teachers serving low-income communities. This proposal will help our neediest schools recruit and retain highly qualified teachers in fields that have critical teacher shortages, as well as fields that face fierce competition from the private sector.

TAX-RELATED ASSISTANCE IN PAYING COLLEGE COSTS

In addition to grants and loans, postsecondary students and their families benefit from a variety of tax-related assistance in paying college costs passed as part of President Bush's tax proposal in 2001. Under the new tax law, families are able to make tax-free withdrawals from pre-paid qualified State tuition savings plans, and can contribute up to $2,000 to Education IRAs. Plus, students are eligible for up to $4,000 in above-the-line deductions for higher education expenses. The tax bill also eliminated the 60-month limitation on student loan interest deductions and increased the income levels of individuals able to claim the deduction. This change makes this tax benefit simpler to administer and increases the affordability of student loan repayment. Additionally, the bill extended the income exclusion for employer-provided educational assistance and the benefit of the exclusion to graduate level courses. Combined with other tax benefits already on the books, over $10 billion this year in tax breaks will be provided to working families who are struggling to meet the skyrocketing cost of college and to students who are repaying their student loans. The President's 2004 Budget would make the important benefits provided in the 2001 tax law permanent.

HISTORICALLY BLACK COLLEGES AND UNIVERSITIES AND HISPANIC-SERVING INSTITUTIONS

Our $224 million request for the Strengthening Historically Black Colleges and Universities program demonstrates the President's commitment to help close achievement and attainment gaps between minority students and other students by assisting institutions that enroll a large proportion of minority and disadvantaged students. Similarly, a $94 million request for Hispanic-serving Institutions would help increase academic achievement, high school graduation, postsecondary participation, and life-long learning among Hispanic Americans.

Overall, the President's 2004 higher education budget proposal further demonstrates his commitment to invest in the future of America's neediest students at all levels of education. The substantial funding increase we are seeking will help millions of needy families pay for higher education and give millions of students the opportunity to pursue their educational goals and make the most of their potential.

DEPARTMENTAL MANAGEMENT—CLEAN AUDIT

While No Child Left Behind reforms are asking States and schools to improve their accountability in the use of education funds, we have tried to set an example by improving our own management. Just last month, the Department of Education received its first clean audit since 1997 and only the second in the history of the Department.

PRESIDENT'S MANAGEMENT AGENDA—"GREEN LIGHT"

I am also proud to report that the Office of Management and Budget has given the Department its seal of approval by giving us a "green light" for our progress in improving management on all items in the President's Management Agenda. This is especially rewarding since we had to work our way up from the bottom on each of the initiatives, ranging from financial management to electronic government to linking program performance and budgeting.

PROGRAM ASSESSMENT RATING TOOL

Also, in the 2004 Budget, the Administration launched the Program Assessment Rating Tool (PART) process to rate programs according to performance. The President's goal was to rate 20 percent of all Federal programs in the first year. In the 2004 Budget, the Department of Education rated 18 programs, covering $28 billion, or more than half of its appropriation. One finding was that many programs lacked performance information. We will work on that in the future, because the PART scores tend to fluctuate based on the strength of data about program success. The PART is a new process and we look forward to increasing our ability to base budget decisions on program effectiveness.

I believe we have a strong budget for education in fiscal year 2004, one that puts significant resources where they can do the most to help improve the quality of educational opportunities at all levels of the American education system. I will be happy to take any questions you may have.

RURAL EDUCATION

Senator SPECTER. Well, Mr. Secretary, thank you for those comments. The critical aspect of what you said is that you will work with us so long as it is within the total figure. And that is the problem, as to how to stretch the dollars to reach so many of these programs which will have to be cut.

Where there is such a major challenge with rural education, how can we justify the elimination of the entire program with a $167 million cut? Rural education is important not only to Iowa, the ranking member's State, or Kansas, but also my home State, Pennsylvania, which has more people living in rural Pennsylvania, 2.5 million, than any State in the Union. How can we go back to justify that to our constituents?

Secretary PAIGE. Yes. Mr. Chairman, let me respond to that by using Alaska as an example, but the same thing will be true for many of the other rural States. And we are learning a lot about rural States, and we are moving now to have discussions specifically about that topic, about rural education.

The various representatives from these States have had a chance to sit down with us, and we with them, to learn about their idiosyncratic issues. We have learned an awful lot about these States. And we are continuing to learn how we can be helpful to the States. They have enlisted the help of very capable accountability experts and are making noble efforts to include all students in their accountability efforts.

Alaska has proposed a comprehensive accountability plan designed to hold all schools, even small schools, accountable. And what they are finding is a Department of Education that is willing to serve as a partner with them to help overcome some of these difficulties. And the same thing is true with Nebraska.

Senator SPECTER. Mr. Secretary, how does accountability bear on eliminating the funding for a program? Mr. Secretary, would you give us a written answer there? We have a very limited amount of time.

Secretary PAIGE. Absolutely. I look forward to that, because I think there are answers. And I would like very much to have a chance to——

Senator SPECTER. If you would provide it in writing, I would appreciate it.

Secretary PAIGE. Absolutely. We will do that.

[The information follows:]

ELIMINATION OF RURAL EDUCATION PROGRAMS

We believe that providing funds through the large formula grant programs, coupled with flexibility in using the funds, is the most effective way to help rural districts to ensure that their students meet challenging State academic content and student achievement standards. No Child Left Behind (NCLB) is intended to encourage a more comprehensive education reform strategy responsive to specific local needs. We believe that school districts will identify problem areas, adopt scientifically based improvement strategies, and use the flexibility of the NCLB Act to combine Federal, State, and local resources to support those strategies. In this context, the important question is not whether a specific program receives a particular level of funding, but whether local officials make effective use of the total resources available.

In addition, recognizing the different needs of small, rural districts, NCLB provided those districts with greater flexibility in their use of Federal formula funds than is available to other districts. For example, a district eligible for the Small, Rural School Achievement program can consolidate its formula allocations from three different programs (Improving Teacher Quality State Grants, Educational Technology State Grants, State Grants for Innovative Programs, and Safe and Drug-Free Schools and Communities State Grants) to carry out activities authorized by any of the consolidated programs. In addition, rural districts are able to use the consolidated funds for activities authorized under Title I, Part A program, the Title III (Language Instruction for Limited English Proficient and Immigrant Students) program, and 21st Century Community Learning Centers.

Unlike districts that transfer funds under the State and Local Transferability authority, the rural flexibility authority enables eligible districts to carry out activities under the various authorities without having to meet separate program requirements. We know from discussions with States that eligible districts are taking advantage of this increased flexibility.

Rural districts not eligible for the rural flexibility authority may use the flexibility allowed by the new State and Local Transferability Act, which allows a district not identified for improvement under Title I to transfer up to 50 percent of its allocation from four different formula programs to any of those programs or to use those funds for Title I, Part A purposes.

GEAR UP

Senator SPECTER. The GEAR UP Program is also cut. That is the other end of the spectrum, moving from rural education to inner city. The GEAR UP Program has been advanced by Congressman Chaka Fattah on the House side, and this subcommittee has added enormous funds to it. GEAR UP seeks to intervene with seventh graders who come from disadvantaged backgrounds, to provide mentoring and close monitoring of individuals to try to work with them through the next 6 years of their education before college and then go on to college.

It seems to me that that is exactly the kind of a program we ought to be emphasizing, where those inner city youth are most at risk. Now should we not be adding funds to programs like that instead of cutting?

MENTORING INITIATIVE

Secretary PAIGE. Yes. And that is why the President's mentoring initiative is such an important part of our request. What is in-

cluded is, I think, $300 million over 3 years for a mentoring program specifically for middle school students, where the need is greatest, and to recruit mentors from all across the spectrum of professional people who love children and are willing to work with them. It is one of the most exciting mentoring programs that we have seen anyplace.

So mentoring is a great concept. In fact, we believe that the most important determinant of a child's success or failure is the quality of the adult relationships in their lives. And mentoring fills that gap. So, far from not thinking it is a good idea, we think it is a superb idea.

FLEXIBILITY OF NO CHILD LEFT BEHIND

Senator SPECTER. Mr. Secretary, let me move to one more question before my time expires, because I am going to observe the time, I will expect other members to do so as well.

Yesterday there were some representatives here, in what they call the Creative Coalition, emphasizing education. And the group had a number of high-powered performers. One of them was Ron Reagan, Jr., another of whom was Fran Drescher, who made a very impassioned plea for funding for the arts in schools. And she was almost poetic in her characterization of the issue, trying to get young people to love themselves instead of loathing themselves, trying to be productive instead of destructive.

The question is: How can we structure funds from the Department of Education to encourage or perhaps—well, "mandate" is a word we do not like to use in the Federal Government, telling people what to do in schools—but to see to it that there is more creative work on this very critical aspect of the educational process, which is significantly ignored?

Secretary PAIGE. Yes. Mr. Chairman, I think many people miss the power of the creativity that is unleashed by the flexibility in the bill, the No Child Left Behind Act. It provides an opportunity for people at the scene, the local level, who choose to focus on arts or focus on other activities, or to be able to use funding flexibly to support that. The amount of funding overall is up. The flexible funding actually is a reallocation of funds, and putting it in localities so that it can be used by those who are on the scene who can make the judgments on where these funds would be best used.

There are places across our Nation that have high interest in the arts. There are places that have interests in other priorities. Each of these things can be met by the flexibility in the bill. So if we just judge, make a judgment, that there is not a category with arts in it and a large number attached to it, we fail to focus on the fact that that possibility exists through election by the people who are at the local level and who are best able to make those judgments.

IMPORTANCE OF READING AND READING INSTRUCTION

Senator SPECTER. Is art as important as reading?

Secretary PAIGE. I think reading is a fundamental activity. I think it is the one upon which all other learning is based. And if a child fails to read and fails to read early, all of the other activities, I think, are made much more difficult. And that is why the President has focused so heavily on reading. About 50 percent of

our special education students are there because they cannot read or have never been taught to read properly. If we can conquer the reading problem substantially, we will reduce the other problems.

Senator SPECTER. Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman.

FISCAL YEAR 2004 BUDGET REQUEST

Mr. Secretary, in your prepared statement and also in your verbal statement here before us this morning—let me get back to it and read it. You said that the President's 2004 budget request is "somewhat unusual in that it was developed before the Congress completed its work on the 2003 appropriation. The request for the Department of Education reflected the administration's relative priorities, at the time, within the overall 2004 discretionary total."

Secretary PAIGE. Yes.

Senator HARKIN. You said that. It is in your statement.

Secretary PAIGE. Absolutely.

Senator HARKIN. You also said, and I made note of this, "We are prepared to work with Congress to adjust some of these priorities"——

Secretary PAIGE. Yes.

Senator HARKIN [continuing]. "In light of the 2003 appropriation"——

Secretary PAIGE. yes.

Senator HARKIN [continuing]. "As long as overall discretionary appropriations do not exceed the total in the President's budget."

Secretary PAIGE. Yes.

Senator HARKIN. Well, in plain English, what you are saying is that the President would support cutting funding for some other Cabinet agencies to increase funding for education. Is that right?

TOTAL EDUCATION BUDGET REQUEST

Secretary PAIGE. I think it would be best to characterize my thoughts about that in this fashion: That given all of the other competing priorities for funds, the appropriate funds to support education would be the $53.1 billion that the President has recommended.

ADJUSTMENTS TO FISCAL YEAR 2004 EDUCATION REQUEST

Senator HARKIN. Oh. Oh, so you are not saying that you want any—wait a minute. Let me go back to this statement. You said that "we would work to adjust these priorities." You do not mean any more money. You say—what you have requested in the budget is the maximum. That is what you just said just now.

Secretary PAIGE. Yes. What we request in the budget is our view of the appropriate funding level for education. Some of the categories inside the request might be higher, viewed as having a higher priority than others. Those kinds of adjustments are entirely possible.

Senator HARKIN. Oh, I see. Let me get this straight. What you are saying, Mr. Secretary, is that when you are talking about adjusting some of these priorities, you are talking about within that amount that you submitted.

Secretary PAIGE. Yes.

Senator HARKIN. You are not saying that you could get any more than that.

Secretary PAIGE. Yes. I am saying that it is our view——

Senator HARKIN. That is not what your written statement said. Your written statement said the request for the DOE——

Secretary PAIGE. Yes.

Senator HARKIN [continuing]. "Reflected the administration's relative priorities, at the time, within the overall 2004 discretionary total."

Secretary PAIGE. Yes.

Senator HARKIN. And you said, "We are prepared to work with Congress to adjust some of these priorities, as long as overall discretionary appropriations," that is, total——

Secretary PAIGE. Yes.

Senator HARKIN [continuing]. "Do not exceed the total in the President's budget." So what that says to me is that the President, and you, are saying that you are willing to increase funding for the Department of Education as long as you cut it someplace else. Is that right, or that is not right?

Secretary PAIGE. Yes, that is exactly right. That is what we are saying.

Senator HARKIN. You are—oh. So this is different than what you just said about 2 minutes ago.

Secretary PAIGE. Okay.

Senator HARKIN. Let us see if we can speak to each other here.

Secretary PAIGE. Okay. Let us try that.

Senator HARKIN. Let us try to speak to each other.

Secretary PAIGE. Okay.

Senator HARKIN. Are you saying that the President would be willing to cut some funding in other Cabinet agencies to increase funding for education?

Secretary PAIGE. No.

We are speaking about the $53.1 billion for education and adjusting the priorities within it.

Senator HARKIN. Oh, I see.

Secretary PAIGE. Yes.

Senator HARKIN. The President will not support more than $53.1 billion.

Secretary PAIGE. I am not speaking for the President with regard to that statement. The statement that I am making is that within the $53.1 billion in our budget, it is our view of the appropriate spending level for education. And inside that $53.1 billion, adjustments——

Senator HARKIN. Well, that is not what your statement says.

Secretary PAIGE. Give me just a minute. Give me just a minute.

Senator HARKIN. That is not what your statement says. But we have to figure this thing out. I am just trying to get a handle on whether or not we might have some hope here. Is hope alive or not?

Secretary PAIGE. Okay. Let me try it again. And I have some more counsel here.

ADJUSTMENTS TO THE FISCAL YEAR 2004 EDUCATION REQUEST

Within the overall President's budget, we can work with some adjustments in education. It might go higher than $53.1 billion for education, as long as the overall spending in the budget does not increase.

Senator HARKIN. Then back to my point: If that is the case, then there has to be some cuts in other Cabinet agencies.

Secretary PAIGE. That is true.

Senator HARKIN. And the President would be willing to support that.

Secretary PAIGE. That is right.

Senator HARKIN. Do we have any suggestions where the President might be willing to cut other departments, so that we can have more money for education?

Secretary PAIGE. We do not have those suggestions presently.

Senator HARKIN. Could we expect to get something like that from the administration?

Secretary PAIGE. I am sure we can.

Senator HARKIN. Well, this committee, I am sure, Mr. Chairman, would love to have some guidance and some suggestions from the administration, since we appropriate money for all of the Cabinet agencies—not our subcommittee here, but the full Appropriations Committee—about where we might cut some of the other departments to get money for education. To me, that is encouraging. Thank you.

Secretary PAIGE. Mr. Harkin, if I could, the Office of Management and Budget has been working with us. And I think the same way in which we worked with you on the development of the 2003 bill, when the education budget went up and there were other priorities, but it stayed within the President's overall amount. During the appropriations process, the administration will be happy to work with Congress as long as the overall President's number remains the same.

Senator HARKIN. Thank you.

Thank you, Mr. Chairman.

Senator SPECTER. Senator Murray.

Senator MURRAY. Well, thank you, Mr. Chairman.

I assume from that conversation then that we can expect to see a revised budget request from the Department of Education.

Secretary PAIGE. No. We are saying that we are willing to work with the Congress and talk to you about those issues.

Senator MURRAY. But you are not going to give us a formal request of any kind so that we know how the President wants to set these priorities?

Secretary PAIGE. That is correct.

FUNDING FOR TEACHER QUALITY IMPROVEMENT

Senator MURRAY. Well, okay. That makes it difficult for us, as we try and manage this. But let me ask you about one of the biggest challenges that I am hearing from the people in my State. They are struggling to meet the requirements to have all teachers and most paraprofessionals highly qualified by 2005, which feels like it is fast approaching.

Do you not agree that fulfilling that kind of mandate will require significant investments in training and recruiting and retaining and testing teachers in order to meet that requirement that we have put forward, that all teachers and most professionals have to be highly qualified by 2005?

Secretary PAIGE. Yes, I do agree it will take significant resources. And that is why the $4.5 billion in the President's budget is there.

Senator MURRAY. But what I see in the President's budget is your request of $2.85 billion for Title II teacher quality, which is what the mandate was under the bill. Last year we actually funded, in 2003, $2.95 million. So your request is below what we funded in 2003. Now I know that you said that you had to prepare this before we did the 2003 appropriations.

Secretary PAIGE. Yes.

Senator MURRAY. And despite the conversation you just had with Senator Harkin, given that you are not going to send us a revised budget, your budget actually calls for $2.85 billion—which is less than we just appropriated for this year for meeting this requirement. I do not see how our schools are going to meet the requirements to have all our teachers and professionals highly trained when we are providing them less money to do it.

Secretary PAIGE. When we discussed Federal funding for teacher quality, preparation, and recruiting and retention, we have to look at the full gamut of support available in the budget for that purpose. And when you do that, it will total $4.5 billion, not just the $2.85 billion.

Mr. HANSEN. And if I might add, Senator Murray, that is an increase even over and beyond the $4.25 billion that is in the current 2003 bill. If you look at our proposals on teacher loan forgiveness, our troops-to-teachers, transition to teaching, other proposals, and total what is provided for in our Title I program with the 5 percent set-aside for teacher training——

Senator MURRAY. With all due respect, let me just tell you that when we worked on the No Child Left Behind, the authorization for this requirement and this money were under the Teacher Quality State Grants. What you are now saying to us is that we are not going to pay attention to the language of the bill and the Teacher Quality State Grants. We are going to pull money from all these other things that we do, and say that that counts.

Well, that is—you know, the schools are already using those funds for specific things. We have added a new requirement, a new accountability requirement, on top of that. And now you are just saying: Use the money you use for something else. That is what it sounds like to me that you are saying to our schools.

Secretary PAIGE. No. We are not saying that. What we are saying is: All of the dollars in the budget for teacher quality improvement are not captured under that line item that includes the $2.85 billion. There are other places.

Senator MURRAY. When we wrote the No Child Left Behind, the teacher quality money was under the Teacher Quality State Grants. That is what we expected to work with the administration in good faith to increase the funding for.

Mr. Chairman, I know we do not have much time. I have a number of other questions I will submit for the record.

PUBLIC SCHOOL CHOICE REQUIREMENTS

But I do have one question in particular that I wanted to ask about, because a lot of our schools, in trying to implement the public school choice requirements, are following your guidance. And your guidance says, and I am going to quote it, "Lack of capacity and health and safety concerns, including overcrowding problems, do not excuse an LEA from meeting the Title I public school choice requirement."

Well, I know you are an educator. And you cannot believe that it makes sense to transfer students to schools that are overcrowded even to the point of causing health and safety concerns. So I am very concerned about that language in your guidance, and I want you to clarify it for us.

Secretary PAIGE. Our language in the guidance was as flexible as we could make it under the language in the law. And so what we were doing there was trying to provide as much flexibility as the law permits us to provide in the capacity issue. We are fully aware of the problems that capacity presents to teaching and learning.

TITLE IX ADVISORY COMMISSION RECOMMENDATIONS

Senator MURRAY. Well, I am deeply concerned about that. And in my last 30 seconds, I want to just jump to one quick question on Title IX. It is another issue that I have dealt with your office on.

You said recently that you would consider only the advisory commission recommendations on Title IX that are unanimous. And two members, at least two members, of the commission have repudiated their support for a number of those so-called unanimous recommendations in their minority report. And I wanted to find out from you this morning if you will consider those recommendations as unanimous or if you will respect the dissenting views on that question.

Secretary PAIGE. The two persons that you refer to voted for the ones that we agree are unanimous. They were a party to that and had more participation and discussion than anyone there. They were part of——

Senator MURRAY. Well, Mr. Secretary, I have talked——

Secretary PAIGE. They were part of the unanimous vote. That is why it is unanimous.

Senator MURRAY. Well, I have talked extensively to them. And they believe that the way the report was written was not the way that their discussions were going. They have submitted a minority report saying that they have dissenting views on that and do not consider them unanimous. I hope that you take a look at that, because there is a lot of disagreement on that.

Secretary PAIGE. Senator, the other 13 members of the commission thought that their conduct with respect to that was very inappropriate. They voted for those issues that were unanimous.

Senator MURRAY. Mr. Secretary, again, with all due respect, I hope that you look at the language of the minority report. They are very specific in their concerns about how those were worded and what the final outcome of that was.

Secretary PAIGE. The commissioners were advised even before they had their first meeting that we wanted them to reach agreement, consensus, and that those were the issues that were going to be included, and that we are going to consider. Even before they had their first meeting, they were advised about that. And so they were fully aware of what the ground rules were and what the rules of engagement were before the meeting, before the report was prepared.

Senator MURRAY. Will you look at the minority report?

Secretary PAIGE. I am going to look at the issues that were voted on unanimously.

Mr. HANSEN. Mrs. Murray, I think it is important to note, too, that Cynthia Cooper, who is the co-chair of the commission, takes great issue with the representation of the other two commissioners—and I think actually the transcript speaks very clearly as well that everybody knew exactly what they were voting for. And I think Cynthia Cooper spelled it out very clearly in the press conference during the——

Secretary PAIGE. And not only Cynthia Cooper, the other members of the commission as well.

Senator MURRAY. I hope we will have further discussion.

Thank you, Mr. Chairman.

Senator SPECTER. Senator Landrieu.

FEDERAL ROLE IN EDUCATION

Senator LANDRIEU. Mr. Secretary, do you agree that one of the roles of the Federal Government is to try to close the opportunity gap between the affluent districts in this Nation and the disadvantaged districts?

Surely, as your background suggests, you are aware that the local school systems are funded, primarily through property taxes; not in every case, but in most cases throughout the Nation. In those school districts where there is a strong middle class or affluent area, property taxes are paid and therefore schools are fairly well funded. In other areas that are poorer and more disadvantaged, where the property is not as valuable, there is by contrast less money that goes into the schools.

In my view one of the roles of the Federal Government is to try to close that gap and help those children that come from less affluent neighborhoods to actually have equal opportunity to succeed. Do you agree?

Secretary PAIGE. Yes, especially if you mean by that the equity. Our role is to—we have two roles—to ensure equity and to promote excellence. And I would consider what you said ensuring equity.

TAX CREDIT PROPOSALS

Senator LANDRIEU. Well, I am very encouraged by that, because I think that is absolutely what we should be doing. But I am perplexed and confused then about the President's proposals. Two initiatives that I see outlined in this budget from your Department and the President are to expand the Coverdell tax credit and then to give an additional tax credit for up to $5,000 in tuition costs. In order to get the tax credit, you would have to be able to have paid $5,000 in tuition, correct?

How do those two programs, one that you are seeking to expand and one that is brand new, meet the objectives that you just stated?

Secretary PAIGE. Well, we believe that one of our greatest failings in education is tying a child to a school that is not serving them well. And so the President is attempting here, and I agree fully, to provide options for parents, so that if a school is not serving a child well, that child has other options. And this is a vehicle to promote that possibility.

Senator LANDRIEU. Well, let us discuss that a minute. Explain to me how a child that comes from a family that cannot afford even $1,000 for tuition would be helped by these two programs. Go ahead and explain that to me, if you would.

Mr. HANSEN. Well, the——

Senator LANDRIEU. In other words how does the tax credit work for them?

Mr. HANSEN. Senator Landrieu, the tax credit, it needs to be kept in mind, that it is an above-the-line tax credit. So it is specifically targeted to disadvantaged families. And I think it is——

Senator LANDRIEU. Excuse me. Could you start again?

Mr. HANSEN. Sure. It is an above-the-line tax credit for families. It is also important to note that the average tuition——

Senator LANDRIEU. Excuse me. Hold on. Explain what you mean by "above the line"?

Mr. HANSEN. It basically means that they are eligible for it no matter what the rest of their tax is. If they do not owe any tax, they still are eligible for the tax credit.

Senator LANDRIEU. That is true, but in order to get it, do they not have to first pay the tuition?

Mr. HANSEN. That is correct. And that is also——

Senator LANDRIEU. So a parent has to have the $5,000, or up to half of $5,000, to pay for tuition before they can either claim the credit. Explain to me then how the people in this country who have two children and who, let us say, make the minimum wage can afford $10,000 in tuition they must pay to be eligible for this credit.

Try to explain that to me how someone pays rent, buys food and clothes, and then pays $10,000 tuition, what benefit are you are offering them.

Secretary PAIGE. There are—go ahead.

Senator LANDRIEU. Go ahead, Mr. Secretary. That would be good.

Secretary PAIGE. There clearly would be many people where this would be a burden. And they would have to find other sources. This category would meet some of the needs for some of the parents. There are other parents who would have to look to other sources. And there are other sources. This is just one of many mechanisms that are designed to provide options for parents.

Senator LANDRIEU. Well, I will finalize this point with my 37 seconds left. What you just stated, goes in direct contradiction to your goal, which according to your testimony is to help those parents that need the help the most, because the gap is so great. The programs that you are proposing in this budget go against that principle.

I am going to do everything I can to oppose these two programs and instead try to support the public schools, as well as choice for parents, real choice that means something to them.

Thank you.

FISCAL YEAR EDUCATION BUDGET PRIORITIES

Mr. HANSEN. Senator Landrieu, if I could, I think it is important to note that the top three priorities in our budget were a billion-dollar increase in the Title I program, with all money in the targeted program; the billion-dollar increase in the Special Education program, which serves the most educationally disadvantaged children in our country. It also included a $1.9 billion——

Senator LANDRIEU. I——

Mr. HANSEN [continuing]. Let me finish, please—a $1.9 billion increase for our Pell Grant program. Ninty percent of those dollars go to families making less than $40,000. So all of our programs are geared to help those who need it the most. This tax credit, if people do not take it, it does not go to wealthy families. It is opportunities for those families that——

Senator LANDRIEU. I did not say it went to wealthy families. Mr. Chairman, I want to get this on the record. I did not say it went to wealthy families. I do not have a problem helping wealthy families. My problem is when resources are limited we should help the poor families first, the middle-income families second, and the wealthy families third. Your budget does not reflect that principle. I disagree with it.

Mr. HANSEN. Our budget does do that.

IMPORTANCE OF ARTS EDUCATION

Senator SPECTER. Mr. Secretary, my concluding question to you was about focusing on the arts. And reading, obviously, is the critical issue on education of young people. And mathematics is not far behind and so many of the substantive issues, history and civics, health courses. But I would appreciate it if you would direct some special attention to what might be done to stimulate the arts.

I started to tell you about this group of The Creative Coalition. A young woman, Fran Drescher, and young Ronald Reagan, and others make such a compelling case. And the emotionalism and self-worth that comes from theater and art are so important that I would like you to take a special look at it.

Now I am not quite sure how we get there, because we do not direct the local boards as to what they do. But there are ways that we can encourage it, perhaps.

Secretary PAIGE. Senator, we have a special interest in the arts. So we would be happy and pleased to do that.

Senator SPECTER. Okay. We would appreciate that.

ATHLETIC OPPORTUNITIES FOR WOMEN AND GIRLS

The issue on Title IX with respect to athletic opportunities has been of great concern. I appreciate your focus on athletic opportunities for women and girls. It has been really amazing to see the women compete in basketball. In a bygone decade, that would have been thought to be unobtainable. So much of the funds are directed

to men's sports because they are big moneymakers, big television, NCAA, et cetera.

But with what we have now seen as to the competitive capabilities of young women and what a vital part it plays in the educational process and the development of women and girls, I think that is a line which we have to take really very positive steps to promote.

Let me turn to a question, Mr. Secretary.

Oh, do you want to make a comment?

Senator Harkin, sotto voce—in fact, not sotto voce. Everybody in the room heard it.

He has a great article titled: "Strike Up the Band, keep music in schools." And in light of our limited time, we will just make this a part of the record. We will get a copy for you to read, Mr. Secretary.

Secretary PAIGE. Thank you.

Senator HARKIN. I would like to have you read this. It was written by the former CEO of Meredith Publishing Company. It is a great article about the arts and school music. It is really a great article, in light of what the chairman was just saying.

[The information follows:]

[From the Des Moines Register, March 25, 2003]

STRIKE UP THE BAND (AND KEEP MUSIC IN SCHOOLS); IOWA VIEW

(By James A. Autry)

I have just returned from a magical mystery tour in which I witnessed a transformation from the ordinary to the sublime. The thing is, this happens all the time but not many of us get to see it from beginning to end. You have to be in the right place at the right time. I was.

But I get ahead of myself.

First, let me begin with a confession: On Saturday night, March 15, I let go of my adult inhibitions in the midst of 149 teenagers, and screamed myself hoarse.

It happened when the chairman of the Heritage Music Festival at Disneyland announced that the top festival award was being presented to Des Moines Roosevelt High School. I jumped to my feet, pumped my hands in the air and yelled my fool head off.

I was as caught up in the moment, as excited and exhilarated as those band, orchestra and chamber choir students who had traveled to Anaheim on March 12 for four days of fun and festival, and who were taking home the top honors.

Later, I wondered if anyone would notice; if the media would bother with a musical triumph when there's so much to be written and shown about the triumphant world of sports.

I wondered how many people know there are more kids involved in public school music than in all the sports put together.

And I thought about the proposed cuts in music programs, and the havoc that may cause for bands, orchestras, choirs, and choruses as they have cuts and changes in teaching staff, plus diminished resources all around.

I am not attacking the administrators or the school board. I am painfully aware of their difficult choices, and the so-called "Leave No Child Behind Act" puts no emphasis on art and music programs.

My purpose is simply to assert that life is about more than the basic "3 Rs." What students learn from music and art programs can't be taught anywhere else.

As a consultant and author, I work with companies that stress teamwork and cross-functional projects. I tell managers to stop using the metaphor of sports teams, with their superstars and bench-warmers, and think of a band or orchestra in which every player has an important role, in which the greatest accomplishment is the ensemble.

Isn't this what good organizations are about, what a democracy is about, what communities are about?

There is no better education—repeat, no better education—for becoming a productive member of society than participation in a musical ensemble. In a band or orchestra or chorus, no child is ever left behind.

And I know. Our son Ronald, now a senior at Roosevelt, has autism. He's not the most accomplished musician in the band, but he always gives it his best effort. And the band has been a defining activity for him. I can't imagine how his high school experience would have been without band.

While I think of the band as having put a little magic in Ronald's life, that's not the magic or the mystery I started writing about. Just as the awards ceremony was not the high point of the Anaheim trip.

That came earlier in the day when the symphonic band, chamber orchestra and chamber choir performed. My description: an utterly mystical experience.

How else would you explain the transformation of typical teenagers into divinely performing musical ensembles? Picture busloads of young people looking and acting as young people do, dressed in a strangely conformist style (boys in baggy jeans, the waistline relocated somewhere around the the mid-to-lower buttocks, girls with low-cut jeans and bare bellies) and talking with one another in a language hardly intelligible to aging adults.

Then picture those same kids in tuxedos and long, black evening dresses, intensely attentive and concentrating fully on their instruments (or voices) and the directions of the conductor, and producing music of a quality unimaginable from high school musicians back when I was one.

It is a mystical transformation brought about by two factors:

One is the transcendent quality of music that inspires kids to reach beyond themselves to perform at their peak.

The key factor: teachers. I sit in awe of these educators—in this case, Treg Marcellus, Joseph Rich, Sandra Tatge and John Wallag—who devote their lives to bringing forth exquisite music from young people who, when they begin, can't imagine the possibilities of what beauty they can create together.

I wish everyone in Des Moines could have the experience I've just had. They would be proud of the performances and the awards, but they'd be equally proud of how the students behaved and represented our city and state.

I can't imagine school activities that produce more positive, lifelong outcomes than these music programs. They deserve everything we can do to preserve them.

Senator SPECTER. Thank you, Senator Harkin, for insisting on not interceding.

Senator Harkin and I always have a good time, in addition to being very cooperative in how we handle these issues.

CAMPUS CRIME AND CLERY ACT ADMINISTRATION

Now, Mr. Secretary, on the subject of campus crime, we had a particularly heinous rape/murder in Pennsylvania which inspired the parents of the victim to come forward on a crusade, which has been so well focused on trying to inform parents and students who are going to college campuses what kind of risks they might expect. And the Department prior to your administration had not done a very good job in administering these campus crime informational requirements.

We have provided you with $750,000 to provide institutions of higher education with a handbook on how to comply with the Clery Act, I would be interested to know how you intend to use it. Do you have a plan now, or if not, you can submit it in writing, if you have not focused on it? What activist programs do you have to see to it that there is enforcement of the provisions in law related to campus crime?

Secretary PAIGE. Well, we share your view about safety. The Department is developing a handbook on compliance with the Clery Act. We intend to use the funds that you have made available in strict compliance with congressional intent. The handbook will focus on explaining programs and regulations in clear language to

school officials. We are consulting with interested organizations, including Security on Campus and participating institutions. The handbook will be distributed to all higher education institutions immediately after it is completed.

We have some other activities going on as well, including a data collection system to facilitate the submission of campus crime data from postsecondary institutions—this is for the third consecutive year—a help desk to provide institutions with technical assistance, and a website to provide easy access to campus security legislation and regulations and data and resources.

We have an enormous array of activities that are underway to promote campus safety. We are very grateful for the $750,000 that was provided, and we are going to make sure that it is used in strict compliance with your intent.

Senator SPECTER. Well, thank you very much, Mr. Secretary.

PREPARED STATEMENT

Senator Thad Cochran's prepared statement will be made part of the record at this point in the hearing.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, it is a pleasure to have Dr. Paige serving as Secretary of Education. He is doing a fine job, and I look forward to working with him on the Department's budget for fiscal year 2004.

One program I need to mention, because nearly every school in Mississippi is dependent upon its funding, is the Title I program for the education of disadvantaged students. I'm pleased to see an increase of $1 Billion in this program. It is always a challenge, though, to get a share of any increase directed to Mississippi. That is a result of the formula distribution and also the child counts that are used by the department to determine eligible students. I hope this year we can come to a resolution that is fair to my state.

I am interested in, and some of the vocational and technical education leaders in my state are concerned about, the Department's proposal for eliminating the Perkins Vocational and Technical Education Program. These are programs that have been very successful. The Mississippi Department of Education and the vocational and technical education centers have contacted me, and met with my staff. They do not understand how a new formula based program will be beneficial to them. So, as we work through the appropriations process, and the reauthorization process, I hope you will consult with the people currently running these programs.

There are also several small, but critically important education programs in which I have a deep interest.

I'm happy that this year, some are included in the Department's Budget request. I commend the Department, and you, Mr. Secretary, for noticing in particular the benefits of and recommending continued funding for the Ready to Learn Television Program, which provides educational television shows to nearly every child in the United States.

I congratulate you on placing a priority on civic education by recommending funding for the Education for Democracy program. It sponsors the We The People Program here in the United States and the Cooperative Education Exchange Program in almost 30 emerging democracies abroad.

There are however, a number of programs listed in the budget proposal under the heading: "Program Terminations." I know we have difficult decisions to make, but I want you to know about a few of those in which I continue to have an interest.

I understand that the Department plans to streamline as many programs as possible, but school leaders in my state advise me that even with the advantages of flexibility, there is still a need for schools and districts to have direct access to grant making programs and others that are best served through a single source.

The Arts in Education program funds a number of high quality programs that use a small federal contribution to leverage other state and private funding. Most successful has been the relatively new grants to schools to provide arts education in their curriculum. The Department of Education published a collection of studies in

1999 and another one last year, both of which gave us clear evidence fo the value of arts in schools. The variety of advantages are amazing. These include decreased drop out rates, increased academic performance, better interpersonal skills, and higher sensitivity to social issues.

Another Arts in Education program is VSA Arts. This is popular program which supports a national network that assures accessible arts programming for children and youth with disabilities. Each year approximately 4.5 million individuals participate in VSA Arts programs.

The National Writing Project is another program that has not only proven its worth, but I am advised that it consistently receives the highest rating from its official federal review. The fact is, that the modest federal funds that have been directed to this program ($14 Million in 2003) are leveraged as much as 7 times in some areas. The National Writing Project does not dictate a certain method of teaching writing, but it provides a highly trained network of teachers who share proven methods with other teachers. Teachers are energized by this training and become better teachers.

The grant program for foreign languages in schools is another one that I truly hope we can continue to fund. Mr. Secretary, during the celebration of International Education Week, you stated a commitment to the elements of what you called a "world-class" education. Foreign languages taught early and throughout a child's life is a corner stone to that goal. Today we have national security issues that beg a population better prepared to conduct themselves with an international awareness. The experts told us at a hearing in 2000 that college is simply too late. We need to start sooner.

There are other programs of importance, such as those which deal with gifted education, physical education, and school counseling. All of these need our attention.

I hope that during this appropriations process, we can again come to some compromise and continue to fund the programs that have national significance and have proven to be successful.

I know that you have the best interests of our children at heart, and I look forward to working with you.

CHAIRMAN'S CLOSING REMARKS

Senator SPECTER. There are many more subjects. We had a pretty good attendance with the five Senators here this morning on an extraordinarily busy morning at 9 o'clock.

We are going to be proceeding to a full committee hearing, as I said earlier, with Secretary Rumsfeld and Secretary Ridge. And with the customary roller skates around here, I have to go to a judiciary committee meeting for a few minutes to try to confirm Justice Priscilla Owen.

But we thank you for what you are doing. We appreciate your coming from Houston, from a very activist program in education and taking on a very big responsibility. There are many other questions of concern to my State, not only as to the rural education but also as to big city education. We will be having a dialogue with you further and I look forward to an opportunity to invite you to Pennsylvania.

You have been very gracious with your time in the past. And we look forward to working with you, Mr. Secretary.

SECRETARY'S CLOSING REMARKS

Secretary PAIGE. We thank you so much for your leadership. And we invite you and the members of the committee, subcommittee, to contact us if there is any discussion you want to have around any of these issues.

Senator SPECTER. Thank you very much.

Secretary PAIGE. Thank you.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

TITLE I SCHOOL IMPROVEMENT

Question. Does the fiscal year 2004 budget request provide sufficient funds to pay the costs of corrective actions—public school choice, supplemental services, school restructuring, etc.—which must be taken with respect to schools which fail to meet adequate yearly progress standards for 2 or more consecutive years?

Answer. State and local educational agencies have been required to take corrective actions to improve Title I schools in need of improvement since the 1994 reauthorization. We believe that the President's $12.4 billion 2004 request for Title I, an increase of $3.6 billion or 41 percent over the amount provided for the final year of the previous law, is more than adequate to help States and school districts provide the new educational options and carry out the improvement measures required by the NCLB Act.

In particular, by statute, 2004 school improvement funding would double from 2 percent to 4 percent of the overall Title I Grants to LEAs funding. The President's request is large enough to ensure that this increased school improvement funding comes from new funding and not from existing Title I allocations.

Question. How many schools have been affected by this requirement during the 2002–2003 school year?

Answer. We do not yet have precise figures from the States, but a survey conducted last summer, combined with data from earlier years, suggests that roughly 8,000 schools were identified for school improvement in the 2002–2003 school year.

TITLE I CHOICE AND SUPPLEMENTAL SERVICES

Question. Have any localities received waivers from the requirement to provide supplemental services?

Answer. Such waivers may be approved by State educational agencies only if there are no available service providers and the school district is itself unable to provide services. We do not yet have any data on how many waivers have been granted by the States.

Question. What evidence is there that third-party supplemental services providers will be any more successful than their regular public schools in providing Title I services?

Answer. While we do not yet know how successful supplemental educational services will be in raising student achievement, we do know, first, that students are eligible for such services only when their schools have failed, for at least three years, to meet adequate yearly progress requirements. In other words, we know the schools are not getting the job done. And, second, we know that there are service providers that have a strong record of improving student achievement, as demonstrated in part by the willingness of parents to pay for their services.

I also should clarify that supplemental educational services, as the name suggests, are not a replacement for regular Title I services, but additional instruction available to those students with the greatest need for improvement. Students receiving supplemental educational services can continue to benefit from the regular Title I program offered in their schools.

Finally, service providers are subject to monitoring by State educational agencies and must meet performance objectives included in the agreements negotiated with parents. If a particular provider consistently fails to meet its objectives for improving student achievement, few parents are likely to request its services and it will likely lose the State-approved status required for participation in the program.

PARENTAL NOTIFICATION OF PUBLIC SCHOOL CHOICE AND SUPPLEMENTAL SERVICES OPTIONS

Question. Are parents of affected pupils eligible for public school choice and supplemental services options being informed of these options in a timely and effective manner?

Answer. In general, I believe most school districts have made a good-faith effort to notify parents of their children's eligibility for both public school choice and supplemental educational services. Some districts experienced difficulty in this area during the current school year, in part because these are new requirements and districts are still developing appropriate procedures and processes for complying with those requirements. In addition, some States did not post their lists of approved providers until well into the second semester of the school year, making it difficult for local educational agencies to make the services available on a timely basis.

I am encouraged by anecdotal reports in the media of districts responding to complaints by parents by improving notification and increasing the range of options available to parents. I expect this improvement will continue as both districts and parents become more familiar comfortable with the choice and supplemental service requirements. In any case, this is an issue we will follow closely over the coming months and years.

Question. Are the parents typically being offered a substantial range of choices?

Answer. We do not yet have sufficient information to describe a "typical" public school choice program under the NCLB Act. Based on reports in the media, the range of choices offered has varied considerably, depending on such factors as the district's understanding of the choice requirements and the number of eligible schools within the district. I think this is pretty much what we expected, particularly during the first year of implementation.

NO CHILD LEFT BEHIND "REPORT CARD" REQUIREMENTS

Question. What are the costs to States and local educational agencies of meeting the report card requirements of the No Child Left Behind Act?

Answer. These costs will vary considerably based on such factors as the size of the State and district involved and the number and type of schools that must be included in State and local report cards. It is important to remember, however, that report cards are not new to the Elementary and Secondary Education Act, but were required under the previous authorization. The NCLB Act did add some requirements for additional information in the annual report cards, but this reflects only incremental cost increases for an existing activity.

Question. How are most States and local educational agencies disseminating their report cards?

Answer. Information about State and local plans and procedures for disseminating their annual report cards was included in the accountability plan workbooks that each State submitted in January 2003 as part of the consolidated application process. The Department is currently subjecting the plans outlined in these workbooks to peer review, and will have more data on report cards when the peer review process is completed early this summer.

Question. If they are disseminated primarily through the Internet, how will parents and other individuals without home computers and Internet access obtain them?

Answer. We do not yet have any data suggesting that the Internet will be the primary means of disseminating annual report cards. However, the Title I regulations require that States and school districts communicate all school improvement information, including annual report cards, directly to parents through such means as regular mail, and not just through broader means such as posting report cards on the Internet.

Question. May Elementary and Secondary Education Act Title I–A funds be used to develop or disseminate report cards?

Answer. Yes, States and school districts may use Title I, Part A funds to meet the requirements of Title I, Part A of the ESEA, which include annual report cards.

Question. How many States and local educational agencies are currently meeting the No Child Left Behind Act requirements to publish report cards on their performance?

Answer. The Department currently does not have complete data on the number of States and school districts meeting the report card requirements of the NCLB Act. Many States and school districts were producing and disseminating report cards under the previous law, but the NCLB Act required additional information that will likely require modification to these pre-NCLB report cards. The Department will have more data on State and local efforts to meet the new report card requirements once it completes the process of peer reviewing State accountability plans early this summer.

EVALUATION OF 21ST CENTURY COMMUNITY LEARNING CENTERS PROGRAM

Question. The fiscal year 2004 budget proposes $600 million for 21st Century Community Learning Centers, a reduction of $393.5 million from the amount provided in last year's bill. These centers help communities provide extended learning opportunities for students—including after school programs—and related services for their families, such as family literacy. The stated reason for the proposed reduction is that the Department's recent national evaluation of centers revealed shortcomings in the program, in particular related to the academic performance of students attending such programs.

Mr. Secretary, given that the findings from the national evaluation that are your basis for reducing the program are not nationally representative and are only first year findings, is it appropriate to cut this program so significantly, especially given the fact that other studies have found academic improvement and other benefits from such programs?

Answer. The rapid growth in funding for the program over the past few years occurred almost entirely in the context of an increased emphasis on improving student achievement. For example, the 2001 request submitted by the previous Administration, which proposed to more than double the appropriation to $1 billion, was justified by the perceived need to give students in all low-performing schools the opportunity to attend after-school programs to help improve their academic achievement. There was a specific link between the size of the request and the academic benefits expected from that request. In this context, our proposal to scale back the program, on the basis of evidence that it is not achieving those expected benefits, seems entirely appropriate. Preliminary findings from the current evaluation of 21st Century Community Learning Centers, conducted by Mathematica Policy Research, Inc., indicate that the centers funded in the program's first three years, on average, provided academic content of limited intensity and had limited influence on academic performance, no influence on feelings of safety, and no positive impact on student delinquent behavior. Attendance in the programs was found to be low (on average, less than two days per week, even though centers were open, on average, four to five days a week).

Additional analyses compared the outcomes of frequent and infrequent program participants. Frequent participants were more likely to be from disadvantaged households and to want to improve in school; however, analyses did not reveal that more frequent participation led to better outcomes.

The evaluation study uses far more rigorous methodology than other studies cited in the after-school program literature. The evaluation includes an experimental research design (randomly selected participants in programs) for the elementary school portion of the study and a quasi-experimental research design (matched comparison groups) for the middle school portion. Other studies in the literature used less rigorous methodologies (and thus produced less reliable results), often presented highly selective results from small samples, and offered information about outcomes rather than impacts. (In contrast to "outcomes" that provide description information on the performance of those who chose to participate in the program, "impacts" provide evidence of outcomes that are caused by their participation in the program.)

Question. Isn't it true that there were many positive findings from the study, such as more parental involvement and better quality of homework produced that argue against such a reduction?

Answer. The Department did not discount those findings. The report states that the achievement gains of African-American, Hispanic, and female students were very small (with improvements only in math and then by less than 2 points on a 1–100 point scale). While parental involvement is often thought to be important, the study reported no clear evidence that a link to achievement exists.

IMPACT OF CURRENT VOCATIONAL EDUCATION PROGRAMS

Question. Given that the National Assessment of Vocational Education's final report has yet to be released by the Department, will you provide specific information about any possible findings that have led the Administration to conclude that the current vocational education programs are not improving student outcomes?

Answer. Since 1917, the Federal Government has invested in helping States and schools better prepare young people for the future, seeking to ensure that every young person leaves high school with the skills he or she needs to succeed. However, evidence shows that we are failing to adequately prepare our youth for the future. For example:

—Recent NAEP and TIMSS data show little improvement in high school students' relative academic performance. Nationally, the high school graduation rate has declined, with many non-graduates eventually obtaining GEDs or other alter-

native certificates that have less value in the labor market than traditional high school diplomas have.

—Large proportions of high school students enter college, but many fail to complete. The best available data suggest that rates of remediation in college are high, and that students who have taken remedial course work are much less likely to persist and eventually earn a college degree than are other students.

—With regard to employment and earnings, students with higher-level math skills earn substantially more than do students with the same level of educational attainment but weaker skills. A similar pattern exists with regard to reading skills.

—Surveys of firms indicate that many test job applicants and that the proportion of applicants who lack the necessary basic literacy and/or math skills may be growing. Thus, even students who enter the job market directly out of high school must have a strong foundation of academic competencies.

—There is no evidence that vocational course taking, as it has been structured, is likely to address deficiencies in academic achievement or improve rates of college going. The previous National Assessment of Vocational Education (NAVE) Final Report, published in 1994, commissioned and reviewed several studies and found: (1) no relationship between vocational education and academic achievement gains, or a negative effect if students substitute vocational for academic courses, and (2) a similar relationship to postsecondary education. A more recent rigorous evaluation of career academies, representing a broad vision of vocational education, found that these programs did not improve standardized math and reading achievement test scores, had no effect on the graduation rate, and did not increase the proportion of students who enroll in postsecondary education by the end of the first year following high school graduation.

The current structure of the Federal vocational and technical education program is not adequately addressing these issues. The NAVE final report is likely to provide additional supporting evidence of the program's inadequacies.

Question. Are these findings applicable to all groups of students?

Answer. Yes. In fact, while there are significant achievement gaps between low-income and minority students and their peers, the overall academic attainment of all high school students is inadequate and disappointing. Too few students, regardless of their family income, race, or ethnicity, are leaving high school without the skills they will need to succeed in postsecondary education and the job market.

REAUTHORIZATION PROPOSAL FOR SECONDARY AND TECHNICAL EDUCATION

Question. Please explain how the Administration's proposed secondary and technical education program would better prepare a complete workforce, with a broad range of skills that will be needed in the Nation's current and future economy.

Answer. The Administration's proposed Secondary and Technical Education Excellence program would shift the Federal role from supporting traditional vocational education to focusing on improving high school academic achievement and on supporting high-quality technical education programs that span the high school and college levels, thus making sure that students are taught the academic knowledge and technical and practical skills needed to make successful transitions from high school to college and from college to the workforce.

In particular, States would use their Federal formula allocations to make grants to partnership of local educational agencies and community and technical colleges to develop or implement academic/technical education programs that show promise or are effective (or show promise of) in improving students' academic and technical skills, increasing degree attainment, reducing the need for remedial courses at the postsecondary level, and improving employment outcomes. Further, to improve the quality and labor market responsiveness of the curriculum and to make it easier for high school graduates to transition to postsecondary education, the proposed program will promote greater collaboration between technical and community colleges and high schools in planning and delivering technical education coursework for secondary school students, as well as continue to support postsecondary programs for adult, career-changing students.

Creating cutting-edge programs of this kind can be costly and time-consuming for administrators, teachers, college faculty, and business leaders, but the proposed program will provide communities with both incentives and resources to take on the difficult but important task of better preparing our young people for the future.

FISCAL YEAR 2004 BUDGET REQUEST FOR THE SECONDARY AND TECHNICAL EDUCATION EXCELLENCE PROGRAM

Question. Given the proposed reduction of $326 million in vocational education programs and the proposed authority to transfer funds for use under Title I of ESEA, are you concerned that there would be sufficient Federal financial assistance to support effective career and technical education programs throughout the United States; and, if not, why?

Answer. We believe that the 2004 budget request is sufficient for the proposed Secondary and Technical Education Excellence program. Under the current program, $1.19 billion is spread thinly, supporting general expenses like equipment purchases and hiring of staff, but having little direct impact on student learning. The new program would target funds to a smaller number of high-need high schools that show promise for raising student achievement and to community colleges that are able to provide students with high-quality education and training leading to successful employment outcomes.

In particular, at the high school level, the program would provide funds to local educational agencies to develop or implement technical education programs that include the high-level academics that all students need in order to succeed in postsecondary education and the job market. In addition to promoting high-quality community and technical college programs for adult, career-changing students, the program would encourage technical and community colleges to act as more active partners in secondary technical education, both to improve the quality and labor market responsiveness of the curriculum and to make it easier for high school graduates to transition to postsecondary education. Thus, Federal funds would be more tightly focused on promoting the development and implementation of programs that are most responsive to the academic and technical skill demands of the 21st century workforce.

STUDENT AID ADMINISTRATION

Question. The President's 2004 budget request proposes the development of a new, discretionary Student Aid Administration (SAA) account that would consolidate all student aid management costs previously funded through the discretionary Program Administration and Federal Family Education Loan Program (FFELP) accounts and the mandatory Federal Direct Student Loan Programs (HEA Section 458) account. Secretary Paige, could you please explain why the President and the Department are seeking to move the mandatory funds obligated under Section 458 of the Higher Education Act of 1965, as amended, from a mandatory to discretionary account when the Higher Education Act is up for reauthorization this year?

Answer. The current student aid administration budget structure—split among multiple mandatory, discretionary, and subsidy accounts—makes it difficult to hold Federal Student Aid, the performance-based organization within the Department, accountable for reducing program operations costs. The fiscal year 2003 appropriations act took a first step toward rationalizing this structure by unifying discretionary funding for student aid operations in the Student Aid Administration account. We believe that it is appropriate to complete the process in the 2004 appropriation, consistent with the President's management and financial improvement agendas.

Question. Why should this provision be enacted through the appropriations process, instead of taking the regular course through the authorizing committee?

Answer. As noted above, the fiscal year 2003 appropriations act took a first step toward rationalizing the funding structure for student aid operations by unifying discretionary funding in the Student Aid Administration account. Completing the process in the 2004 appropriation is a key component of the President's budget, management, and financial improvement agendas.

Question. One of the purposes identified by the Congress for establishing the Performance Based Organization (PBO) was to improve service to students and other participants in the student financial assistance programs authorized under title IV of the Higher Education Act. Given that administrative expenses for the PBO are closely associated with the number of loans issued in a given year—a level which could be difficult to predict—how will the proposal to make administrative expenses subject to annual appropriations better achieve that purpose behind the creation of the PBO?

Answer. Mandatory administrative funding levels are typically set for 5-year periods, and for the past few years have been straightlined except for growth in guaranty agency administrative payments. We believe that setting funding levels as part of the annual appropriations process will actually allow greater flexibility to ensure

that sufficient funds are available to provide the best possible service to student aid program participants.

The Administration is developing a true activity-based budget formulation process for student aid administration to better incorporate Department workload projections in its annual budget request. (The number of loans in a given year is but one of a large number of variables, including the number of student aid applications, awards, loans in default, Direct Loans in repayment, etc., that determine student aid administrative costs.) This process will also allocate student aid management expenses to specific business processes, allowing the Department to more accurately determine the cost of individual activities or programs, and facilitating efforts to budget administrative funds to each business process, set cost reduction targets, and easily compare actual performance to budget targets.

STUDENT AID APPROPRIATIONS AND ADMINISTRATIVE COSTS

Question. What happens if funds appropriated fell short of the amount required to meet the operations of the PBO?

Answer. We are confident that Department managers will be able to operate their operations effectively within the requested funding level. The Department has long experience managing program operations with discretionary funds—as you know, it is already the case with the Department's program administration funds and, indeed, virtually all other administrative appropriations in the entire government.

Question. How would services to students and other participants be affected?

Answer. We do not expect that this proposal would affect service to students, schools, and other student aid program participants. This is a management improvement designed to improve program efficiency while being transparent to program beneficiaries.

STUDENT FINANCIAL ASSISTANCE: PELL APPLICANT GROWTH AND PROJECTED PELL FUNDING SHORTFALLS

Question. Given the unexpected 9 percent and 10 percent growth in the Pell Grant program over the past two years, do you expect that your estimates of 25 percent applicant growth in the coming academic year and 1.5 percent for the following year create a shortfall greater than the one estimated under the President's budget request?

Answer. The Administration believes that the applicant growth estimates underlying the President's Budget request for Pell Grants are prudent assumptions based on an analysis of historical trends. During the previous period of Pell Grant funding shortfalls—from academic years 1990–91 to 1993–94—the applicant growth rate increased cumulatively by 22.5 percent, or at an annual average of 5.6 percent. Immediately following this period of (then) unprecedented applicant growth, the number of Pell applicants grew by only 1.4 percent in academic year 1994–95. Furthermore, applicants grew only 13 percent during the 7-year span between academic years 1994–95 and 2000–01. The average growth rate per award year for this 7-year period was 1.6 percent.

During the current funding shortfall, Pell applicants increased cumulatively by 18.6 percent during award years 2001–02 and 2002–03. Based on historical data, the Department's applicant projection for AY 2004–05 assumes a similar pattern of decline immediately following cumulative surges, as recorded during the last funding shortfall. In addition, given the recent cumulative growth among older, independent students and projected population figures for students in the traditional college age cohort, it is possible that the pool of Pell applicants not already receiving awards will begin to shrink.

PELL GRANT FUNDING HISTORY

Question. Over the life of the Pell Grant program, how often have there been annual funding shortfalls, as reported in Pell Grant End-of-Year (EOY) Reports?

Answer. A comparison between total expenditures and appropriation level for a given award year in the Pell Grant EOY Report does not accurately portray the cumulative funding shortfall or surplus since prior-year unobligated funds may be used in current years and funds from future appropriations are often used to cover current year shortfalls. Moreover, appropriation levels are often determined based on the estimates of prior-year shortfalls and surpluses, in addition to the estimated current year program cost.

A table from the Award Year (AY) 2000–01 Pell Grant EOY Report is provided, however, to illustrate the total expenditures, appropriation level, current year shortfall/surplus, and the reduction method employed to help alleviate Pell Grant shortfalls.

An additional table is provided to show a more accurate portrayal of the Pell Grant shortfalls and surpluses dating back to 1989. These data are taken from final budget documents and financial systems, illustrating cumulative shortfall and surplus amounts over time.

HISTORY OF PELL GRANT FUNDING: AY 2000–01 EOY REPORT

Fiscal year	Award year	Total expenditures [1]	Appropriation	Current year surplus/ (shortfall)	Action
1973	1973–74	$48,469,000	$122,100,000	$73,631,000	Stepped Reduction
1974	1974–75	361,188,000	475,000,000	113,812,000	Stepped Reduction
1975	1975–76	932,083,000	840,200,000	(91,883,000)	Full Funding
1976	1976–77	1,485,164,000	1,325,800,000	(159,364,000)	Full Funding
1977	1977–78	1,534,395,000	1,903,900,000	369,505,000	Full Funding
1978	1978–79	1,550,360,000	2,160,000,000	609,640,000	Stepped Reduction
1979	1979–80	2,369,911,375	2,431,000,000	61,088,625	Full Funding
1980	1980–81	2,400,656,660	2,157,000,000	(243,656,660)	Flat $50 Reduction
1981	1981–82	2,313,263,380	2,604,000,000	290,736,620	Flat $80 Reduction
1982	1982–83	2,433,130,730	2,419,040,000	(14,090,730)	Stepped
1983	1983–84	2,810,851,530	2,419,040,000	(391,811,530)	Full Funding
1984	1984–85	3,066,734,552	2,800,000,000	(266,734,552)	Full Funding
1985	1985–86	3,611,447,366	3,862,000,000	250,552,634	Full Funding
1986	1986–87	3,473,304,086	3,579,716,000	106,411,914	Linear Reduction
1987	1987–88	3,768,737,216	4,187,000,000	418,262,784	Full Funding
1988	1988–89	4,491,684,679	4,260,430,000	(231,254,679)	Full Funding
1989	1989–90	4,794,454,987	4,483,915,000	(310,539,987)	Full Funding
1990	1990–91	4,952,215,055	4,804,478,000	(147,737,055)	Linear Reduction
1991	1991–92	5,811,633,979	5,375,500,000	(436,133,979)	Full Funding
1992	1992–93	6,195,912,589	5,502,800,000	(693,112,589)	Full Funding
1993	1993–94	5,673,231,640	6,461,900,000	788,668,360	Full Funding
1994	1994–95	5,537,849,327	6,636,700,000	1,098,850,673	Full Funding
1995	1995–96	5,489,766,815	6,146,800,000	657,033,185	Full Funding
1996	1996–97	5,798,361,158	4,914,000,000	(884,361,158)	Full Funding
1997	1997–98	6,349,755,300	5,919,000,000	(430,755,300)	Full Funding
1998	1998–99	7,252,057,389	7,344,900,000	92,842,611	Full Funding
1999	1999–00	7,039,119,041	7,704,000,000	664,880,959	Full Funding
2000	2000–01	7,975,801,349	7,640,000,000	(335,801,349)	Full Funding

[1] Total Expenditures also include Administrative Cost Allowance (ACA) payments.

Note: Since prior-year unobligated funds may be used in current award years and funds from future appropriations may be used, fiscal year appropriation levels are often based on estimates of prior-year funding shortfalls and surpluses—in addition to the estimated current year program cost. Therefore, the comparison between total expenditures and appropriation level may not provide an accurate representation of funding shortfalls and surpluses Moreover, obligation levels continue to fluctuate after the EOY Report has been printed.

HISTORY OF PELL GRANT FUNDING SURPLUSES/SHORTFALLSBASED ON BUDGET/FINANCIAL SYSTEMS: FISCAL YEAR 1989–2003

Fiscal year	Award year	Annual surplus/ (Shortfall)	Cumulative Surplus/ Shortfall	Action(s) taken for cumulative shortfall
1989	1989–90	($75,366,675)	.....	
1990	1990–91	($230,367,465)	($305,734,140)	Fiscal year 1991 funds used.
1991	1991–92	($396,568,870)	($702,303,010)	Fiscal year 1992 funds used.
1992	1992–93	$18,219,444	($684,083,566)	Fiscal year 1993 Appropriation ($240M); fiscal year 1993 Supplemental Appropriation ($341M); Transfers ($9M); fiscal year 1994 funds used.
1993	1993–94	$459,709,140	($224,374,426)	Fiscal year 1994 Supplemental Appropriation ($250M); Transfers ($3.1M).
1994	1994–95	$807,731,000	$583,356,574	
1995	1995–96	$715,845,000	$1,299,201,574	
1996	1996–97	($864,440,000)	$434,761,574	
1997	1997–98	($396,000,000)	$38,761,574	
1998	1998–99	$123,934,000	$162,695,574	
1999	1999–00	$474,000,000	$636,695,574	
2000	2000–01	($317,283,000)	$319,412,574	
2001	2001–02	($1,242,000,000)	($922,587,426)	Fiscal year 2002 funds used.
2002	2002–03	($310,000,000)	($1,232,587,426)	Fiscal year 2002 Supplemental Appropriation ($1B); fiscal year 2003 funds will be used.
2003	2003–04	($305,353,000)	($1,537,940,426)	Fiscal year 2004 funds will be used.

Notes: Funding surplus/shortfall amounts reflect supplemental appropriations, rescissions, and transfers
Data for award years 2002–03 and 2003–04 are estimates based on assumptions used in the President's fiscal year 2004 Budget and final fiscal year 2003 action.

Question. Please outline how each of those shortfalls has been addressed?

Answer. As shown in the first table above, the Pell Grant maximum award has been reduced in eight award years, by various methods, due to insufficient funding. The additional table lists supplemental appropriations, transfers, and other steps taken during the years of cumulative shortfalls.

PELL GRANT MAXIMUM AWARD AND COST OF HIGHER EDUCATION

Question. Does your proposal to establish a maximum Pell Grant at $4,000 for fiscal year 2004 mean that students served by the program will lose ground relative to the price of postsecondary education?

Answer. Since 2000, the increase in the Pell Grant maximum award has matched the increased average cost of attendance at 4-year public institutions. We will work with our partners in States and institutions to ensure students—especially the most needy students—retain access to quality postsecondary education.

FISCAL YEAR 2004 EDUCATION BUDGET REQUEST AND STUDENT ACCESS TO POSTSECONDARY EDUCATION

Question. The fiscal year 2004 budget request reduces funding for Supplemental Education Opportunity Grants, Federal Work-study, the Perkins loan program, GEAR UP and TRIO programs. In addition, the budget proposes reducing the maximum Pell Grant award to $4,000. The Nation's neediest students are the ones supported by these programs. How does the Administration justify reducing and in some cases eliminating funding for these programs at a time when State budget reductions are forcing higher tuitions and fees and there is a rapidly growing population of needy students that want and should go to college?

Answer. Because the fiscal year 2004 budget request was prepared before the fiscal year 2003 appropriation was finalized, it was based on the Administration's fiscal year 2003 budget request. As a result, in a number of cases where the actual appropriation exceeded the 2003 request, the Administration's intent to provide level funding in fiscal year 2004 now appears to be a decrease in support. (This is true for the Pell Grant maximum and the Supplemental Education Opportunity Grant (SEOG), TRIO and GEAR UP programs. Our request for Federal Work-Study would be an increase over the final fiscal year 2003 level.) The Administration is prepared to work with Congress to adjust priorities in the fiscal year 2004 budget, but is committed to maintaining an overall discretionary spending limit that is consistent with the Administration's request.

That said, our priority for 2004, as it has been for the past few years, is the Pell Grant program, the largest and most need-based of Federal student grant programs. Accordingly, the President proposed a record $1.35 billion, or 12 percent increase, for Pell Grants, for an all-time high total of $12.7 billion. We believe that concentrating our resources in this way—the Pell increase alone is actually significantly larger than the entire SEOG or Work-Study program, or TRIO and GEAR UP combined—is the most efficient way to help the most needy students.

Question. What other sources of assistance are available under the budget request to continue to provide access to quality postsecondary education for all Americans?

Answer. Under the Administration's fiscal year 2004 budget request, the Federal Family Education Loan and William D. Ford Direct Student Loan programs will provide nearly $47.6 billion in loans to help students and parents pay for postsecondary education. In addition, the request maintains support for several other higher education programs that help to provide access to postsecondary educational programs. The Byrd Honors Scholarships program would receive $41 million under the 2004 request to provide more than 27,000 merit-based scholarships for undergraduate students. The Javits Fellowships and Graduate Assistance in Areas of National Need programs also would receive a combined $41 million to provide merit- and need-based awards for students pursuing advanced degrees. Additionally, the Fund for the Improvement of Postsecondary Education would receive $39.1 million to support a wide range of innovative projects, including many focused on increasing the access and retention of underrepresented students.

ADMINISTRATION'S PROPOSED INCOME TAX PROVISION AND REDUCTION OF ERRONEOUS STUDENT AID PAYMENTS

Question. The Administration has proposed to allow the IRS to match income tax return data against student aid applications, in order to reduce the number of erroneous student aid payments. According to the U.S. Department of Education, this proposal would save the Federal Government $292 million in erroneous payments during the 2003–2004 academic year and $346 million in the 2004–2005 academic

year. What steps have you taken to gain the support of the authorizing committees of jurisdiction?

Answer. We have been working closely with both tax writing committees as well as the Joint Committee on Taxation ("JCT") to enact this proposal. While there is support for the goal of eliminating erroneous payments in the student aid programs, the JCT has raised questions about the privacy implications of allowing Department contractors access to applicant tax data in order to implement the data match. We are working closely with the JCT to demonstrate that the Administration's proposal will actually strengthen protection of applicant tax data versus the current verification process.

OTHER STEPS TAKEN TO REDUCE AND ELIMINATE ERRONEOUS FEDERAL EDUCATION PAYMENTS

Question. What other steps is the Department taking to reduce and eliminate erroneous Federal education payments?

Answer. The Department is taking a number of steps to address the problem of erroneous payments, including working closely with the Office of Management and Budget in implementing Public Law 107–300, the Improper Payment Information Act of 2002. The Act mandates tracking erroneous payments down to the sub-recipient level for grants and all procurements, in addition to loans, loan guarantees, etc. The threshold will be 2.5 percent or $10 million in improper payments, whichever is greater, proven by a statistical sample with a 90 percent confidence level.

LEVERAGING EDUCATIONAL ASSISTANCE PARTNERSHIPS

Question. Mr. Secretary, your budget eliminates the Leveraging Educational Assistance Partnership (LEAP) program. Since nearly all States are facing deficits, tuition rates are being forced up, and research by the Advisory Committee on Student Financial Assistance and others has documented the need for more State/Federal partnership program funding to close the growing college access gap between low- and high-income students, can you tell me why you think eliminating this program is a good idea?

Answer. Since LEAP was first authorized as the SSIG program in 1972—when only 28 States had undergraduate need-based grant programs—the State commitment to providing need-based student aid has grown exponentially. Today nearly all States have need-based student grant programs, with grant levels that have expanded greatly over the years, and most States significantly exceed the statutory matching requirements. For academic year 2001–2002, for example, estimated State matching funds totaled nearly $1 billion, more than $950 million over the level generated by a dollar-for-dollar match, and far more than would be required even under the 2-for-1 match under Special LEAP. This suggests a considerable level of State commitment, regardless of Federal expenditures.

JAVITS FELLOWSHIPS AND GRADUATE ASSISTANCE IN AREAS OF NATIONAL NEED

Question. Mr. Secretary, the Graduate Assistance in Areas of National Need (GAANN) and Jacob Javits programs attract exceptionally promising students into graduate study to pursue degrees in areas of national need—such as chemistry, information sciences, and engineering—as well as in the arts, humanities, and social sciences. The fiscal year 2004 budget request proposes roughly level funding for these programs at a time when supporting advanced study in these areas is of great importance to the Nation. The National Science Foundation (NSF) and the National Institutes of Health (NIH) have proposed increasing their graduate education budgets for fellowships and traineeships. Why have you not done the same, given the important niche these programs serve in the Federal Government's graduate education portfolio?

Answer. The general approach this year was to request increases for selected high-priority programs. Our priority for 2004, as it has been for the past few years, is the Pell Grant program, the largest and most need-based of Federal student grant programs. We believe that concentrating our resources in this way is the best way to help the most needy students. The Administration supports the Javits Fellowships and GAANN programs and recognizes that they play an important role in preparing students for scholarly careers and careers in areas of national need. The funding requested for these programs would support a total of 1,116 fellowships, including approximately 400 new fellowships. However, in light of the current budget conditions, the Administration considered it necessary to demonstrate fiscal discipline and limit program increases to only the highest-priority programs.

RECREATIONAL PROGRAMS FOR INDIVIDUALS WITH DISABILITIES

Question. With a success/sustainability rate of nearly 75 percent, recreational programs have proven to be an effective approach to leveraging local and private funding to support the integration of individuals with disabilities into the community. Budget documents indicate that this program has limited national impact and that funding is more appropriately derived from States, local agencies and the private sector. Doesn't the Federal Government have a specific role in stimulating and leveraging local and private funding for recreational programs that support the community integration needs of individuals with disabilities?

Answer. We do believe that the Federal Government has a role in helping individuals with disabilities become full and active members of society. We have targeted resources on those activities in which the Federal role is critical. For example, the Department is supporting over 20 National Institute on Disability and Rehabilitation Research (NIDRR) projects that include some attention to issues relating to the participation of individuals with disabilities in recreational, physical exercise, or leisure activities. For example, NIDRR just began support for a 5-year $5.4 million Rehabilitation Engineering Research Center on Recreational Technologies and Exercise Physiology Benefiting Persons with Disabilities. This center will study recreational opportunities for individuals with disabilities, interventions to increase physical activity and recreation participation of individuals with disabilities, and strategies to reduce physical activity relapse and dropout rates. The center will be conducting randomized clinical trials to evaluate improvements in health and function.

Another example is the Traumatic Brain Injury (TBI) Model System located at the University of Washington's Department of Rehabilitation Medicine. The project conducts research on the effect of exercise on depression after TBI. This low-cost community intervention seeks to combat depression and emotional distress in persons with stable TBI, by employing exercise as a positive approach to improved emotional and physical functioning and socialization. This 5-year project began in fiscal year 2002 and is budgeted to receive a total of $1.825 million.

CONTINUED AVAILABILITY OF RECREATIONAL PROGRAMS FOR PEOPLE WITH DISABILITIES

Question. What evidence does the Department have that recreational programs for individuals with disabilities would continue to be available to those in need of them without the seed money provided by this program?

Answer. The best evidence the Department has is the track record of the programs we have funded. Grantees are required to provide an increased level of support from non-Federal sources over their 3-year project period. Of the 33 grantees whose projects received their last year of Federal support during fiscal years 1998 through 2000, 24 projects are still in operation and providing recreational services to individuals with disabilities. Even more importantly, most recreation programs have been initiated and sustained without Federal funds.

ASSISTIVE TECHNOLOGY ACT STATE GRANT PROGRAM

Question. State Grant funding provided under title I of the Assistive Technology Act has been critical to building an infrastructure specifically designed to ensure that people with disabilities—regardless of age or disabling condition—have access to the technology devices and services they need to be independent and productive members of society. Without this national infrastructure, there will be unbridgeable gaps in access to Assistive technology devices throughout the country. Why does the Department's budget request propose to eliminate Federal financial support for these activities?

Answer. The Assistive Technology (AT) State grant program was designed to be time-limited. The authority for this program originally authorized 10 years of funding for States. However, in fiscal year 1998 Congress enacted the new Assistive Technology Act in order to provide States with an additional 3 years of funding, among other things. The Administration believes that the AT State grant program has fulfilled its original mission by providing 10 or more years of Federal funding to States to assist them with achieving the goals of AT Act. In fiscal year 2003, all States will have received 10 years of funding and 31 States will have received at least 13 years of funding.

HELPING PEOPLE WITH DISABILITIES ACHIEVE INDEPENDENCE

Question. Numerous technological and policy changes such as the Olmstead decision, Section 508 final guidelines, and the Telecommunications Act Section 255 were not anticipated when the sunset provisions related to Federal support of Tech Act

Projects were originally conceived. Does the Department believe that Assistive Technology State grant projects have a role to play in building an infrastructure that ensures that people with disabilities can be independent and productive members of society?

Answer. The AT State grants program has helped States to increase access to AT services and devices through changes in State laws, regulations, policies, practices, procedures, and organizational structures. State AT Act programs have had over 10 years of experience in developing and implementing AT policies, procedures, and programs that support community integration and full participation of individuals with disabilities in home, work, education, and community settings. States now have a much greater capacity to deal with changes in policy and technology that have occurred since the AT Act was first enacted. The Administration is committed to helping people with disabilities achieve independence through such efforts as the New Freedom Initiative. It has targeted Federal investments on such activities as research and development, through the National Institute on Disability and Rehabilitation Research's Rehabilitation Engineering Research Centers, the AT alternative financing program, which makes loans for purchasing assistive technology available to individuals with disabilities, and dissemination and technical assistance efforts like the NIDRR's Disability and Business Technical Assistance Centers (DBTACs http://www.adata.org/dbtac.htm), which provide information, materials, technical assistance, and training on the ADA and accessible information technology.

Question. If so, what is that role and how will it be carried out without Federal financial assistance?

Answer. Federal support provided under the AT State grants program has played a role in building an infrastructure specifically designed to ensure that people with disabilities, through assistive technologies, have full access to home, work, education, and community activities. States are well positioned to continue to identify consumer needs and address changing trends.

PROGRAMS ELIMINATED IN FISCAL YEAR 2004 BUDGET

Question. The fiscal year 2004 budget request proposes to eliminate 48 categorical grant programs funded at $1.6 billion last year, ranging from the Smaller Learning Communities program and Arts in Education to Rural Education. Many of these programs are programs that were just reauthorized last year as part of the No Child Left Behind Act and have strong congressional backing. Can you explain why you propose to eliminate these programs?

Answer. Major program increases in the 2004 President's budget are offset in part by these proposed program terminations, nearly all of which are narrow categorical activities that have achieved their purpose, have a limited impact, or may be funded through other more flexible State grant programs. Without these reductions, it would be impossible to provide significant increases to major Administration and Congressional priorities such as Title I, Special Education Grants to States, and Pell Grants. In addition, the Administration believes it is more effective to deliver scarce Federal education resources to States and school districts through large, flexible formula grant programs rather than small, categorical grant programs mandating particular approaches to educational improvement.

ASSESSING EDUCATION PROGRAM EFFECTIVENESS

Question. Please provide the subcommittee with the names of and primary findings from the evaluation studies used for identifying ineffective programs. If it is the Department's view that these programs are duplicative of other broader authorities, please provide a list of the eliminated programs, categorized by the broad authorities under which the activities may be undertaken.

Answer. The primary vehicle for assessing program effectiveness during the development of the 2004 President's budget was the new OMB "Program Assessment Rating Tool" (PART), which was developed to help integrate budget and program performance. The PART instrument rated programs based on responses to 26 questions in four areas, including program purpose and design, strategic planning, program management, and program results. PART also relied on evaluation results whenever they were available for the programs under review.

The PART process identified 4 of the Department's programs as ineffective: Even Start, Safe and Drug-Free Schools and Communities State Grants, TRIO Upward Bound, and Vocational Education State Grants. For the Even Start program, the evaluation findings provided the basis for the ineffective rating. The PART assessment found, among other things, that 3 national evaluations of the program (National Evaluation of the Even Start Family Literacy Program (1995), Second Na-

tional Evaluation of the Even Start Family Literacy Program: Final Report (1998), and Third National Even Start Evaluation: Program Impacts and Implications for Improvement (2003)) show that the program has had no significant impact on the children and parents served.

Below is a list of programs authorized in NCLB that the 2004 budget proposed for elimination because they are duplicative or the activities authorized can be carried out under other programs, such as the Title I Grants to Local Educational Agencies, Improving Teacher Quality State Grants, Educational Technology State Grants, and Safe and Drug-Free Schools and Communities State Grants. Also, if States and districts chose to do so, activities supported by most of these programs can be carried out under State Grants for Innovative Programs (Title V–A).

Comprehensive school reform; Close Up fellowships; Dropout prevention programs; School leadership; Advanced credentialing; National writing project; Preparing tomorrow's teachers to use technology; Elementary and secondary school counseling; Smaller learning communities; Javits gifted and talented education; Star schools; Ready to teach; Community technology centers; Parental assistance information centers; State grants for community service for expelled or suspended students; Alcohol abuse reduction; Rural education.

FISCAL YEAR 2004 BUDGET VS. FLEXIBILITY AND ACCOUNTABILITY

Question. Under the State and Local Transferability Act enacted as part of the No Child Left Behind Act, States and local school districts are provided with additional flexibility to target certain Federal funds to Federal programs that most effectively address the unique needs of States and localities, and to transfer Federal funds allocated to certain State grant activities to allocations for certain activities authorized under Title I. How did the Department consider this authority in making its fiscal year 2004 budget request?

Answer. The 2004 budget request maintains high levels of funding for the programs that are included in the transferability authority (Improving Teacher Quality State Grants, Educational Technology State Grants, State Grants for Innovative Programs, and Safe and Drug-Free Schools and Communities State Grants). Supporting State and local efforts to transfer funds is consistent with the Administration's belief that the most effective use of Federal funds is to provide them to States and districts through flexible formula grant programs that target funds to the classroom and allow local districts to use the funds in a manner that best meets their needs. Federal formulas cannot deliver funds to all school districts in amounts that align with their priorities.

STATE AND LOCAL TRANSFERABILITY ACT AUTHORITY

Question. How will the authority be considered in assessing the relationship between Federal funding provided and the performance outcomes achieved with such funds?

Answer. The Department plans to collect information, through program performance reports and a study of resource allocation, on the amount of funds transferred among programs under the transferability authority. Unlike the other flexibility demonstration options, transferability does not require States or districts to submit applications or to meet additional performance goals or separate accountability requirements. Through the statewide accountability system, districts are accountable for making adequate yearly progress (AYP). Transferability is a tool best used as part of a larger strategy for improvement.

As for the relationship between Federal funding and performance outcomes, in general, we believe that it is often not possible to isolate the separate impact of many Federal programs on student outcomes, in due to the fact that Federal programs frequently seek to leverage broader State and local improvements in education programs. However, we will also continue to collect and report information on trends in student outcomes in order to assess the overall impact of Federal, State, and local reform efforts on student achievement.

Question. How will this authority shape decisions on future budget requests for affected programs?

Answer. The transferability authority supports the Administration's emphasis on rationalizing and consolidating the delivery of Federal education resources in order to give States and school districts maximum flexibility in using these resources to meet local needs and improve student achievement while reducing administrative, paperwork, and regulatory burdens. As with the 2004 budget request, I expect that we will work to maintain or increase funding for the flexible State grant programs included in the transferability authority, while reducing budget support for smaller

categorical programs with limited impact and more complex administrative requirements.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

FISCAL YEAR 2004 BUDGET REQUEST FOR EDUCATION

Question. Mr. Secretary, during the March 27 hearing, you agreed after much discussion that the President would be willing to support funding cuts in other Cabinet agencies in order to increase funding for the Department of Education, as long as overall discretionary appropriations do not exceed the total in the President's budget. You stated that you did not have any recommendations at that time about where to make cuts in the other Cabinet agencies, but that we could expect some guidance later.

Given that the Senate Appropriations Committee could begin marking up appropriations bills very shortly, we need that guidance as quickly as possible. Do you have any suggestions for how much money the Committee should add for education, and where it should offset those increases with cuts?

Answer. The President does not intend to change his 2004 Budget that was prepared and submitted to Congress, prior to Congress completing action on the 2003 Omnibus bill. The President's 2004 Budget was developed within a framework that set a proposed total for discretionary spending in 2004, and each agency and program request reflected the Administration's relative priority for that operation within that total. We recognize that Congress may believe there is a need to reorder and adjust some of these priorities, and the Administration intends to work with Congress to develop alternative figures for education programs as you go through the 2004 appropriation process, always within the requirement, however, that whatever is done for Education must fit within the overall President's 2004 budget total for discretionary programs. As Congress considers Education and related programs, I would urge you to consider our recommendations for reducing or eliminating individual categorical programs that have fulfilled their original purpose, proven ineffective, or which are duplicated by other larger, more flexible grant programs. That is a good way to stretch the education dollar.

FISCAL YEAR 2004 BUDGET AND TITLE I FORMULAS

Question. According to the Congressional Research Service (CRS), the Education Finance Incentive Grant funding (EFIG) stream authorized under Title I of the ESEA provides a modest financial reward, or incentive, to those States with education finance systems that minimize disparities in the distribution of State funding. CRS also reports that, in fiscal year 2002, the EFIG formula targeted a higher percentage of its funds to the two highest-poverty quintiles of needy students than any other funding formula (50.4 percent of EFIG funds, compared to 49.8 percent of targeted grant funds).

EDUCATION FINANCE INCENTIVE GRANT FUNDING (EFIG) VS. TITLE I TARGETED GRANT FORMULA

Question. The Department of Education Appropriations Act, 2003, included $1.5 billion for EFIG, while the fiscal year 2004 President's budget reduces this funding to the fiscal year 2002 level of $793 million and instead provides additional funding under the Targeted Grant formula. Given that the education finance funding stream is more targeted to the neediest students than any other formula and provides an incentive to States for reducing disparities in funding streams, why does the Administration propose reducing this funding stream and providing all of its proposed fiscal year 2004 Title I increase under the Targeted Grants program?

Answer. The budget requests the entire increase under the Title I Targeted Grants formula because the formula delivers a larger share of Title I funds to high-poverty local educational agencies (LEAs) than the Education Finance Incentive Grant (EFIG) formula. Increasing the funding for Incentive Grants would simply divert more resources away from the highest-poverty States and districts with the greatest need for Title I funds.

For example, the 10 poorest States by poverty rate account for 41.4 percent of the total population of children in poverty aged 5–17. Based on fiscal year 2003 Preliminary allocations, these 10 States would receive 45 percent of the Targeted Grants funds and only 40 percent of the EFIG funds. By contrast, the 10 States with lowest poverty rate, which account for 6.7 percent of children in poverty aged 5–17, would receive 6.5 percent of the Targeted Grants funds and 7.9 percent of the EFIG funds.

The EFIG formula, added to Title I in the 1994 ESEA reauthorization, includes "effort" and "equity" factors intended to benefit high-poverty districts by encouraging States to spend more on education and to improve the equity of the State funding systems. However, the formula unfairly shifts money from high-poverty States to low-poverty States, and has a very limited impact.

The "effort" factor reduces the targeting of Title I funds to the highest-poverty States, primarily because the lower level of resources available for education in these States (at least on a per-capita basis) produces a lower level of "effort" in the formula. This reduced targeting is diametrically opposed to the purpose and design of the Title I program.

States with the largest and highest-poverty urban centers—including New York, Texas, and California—receive a significantly reduced share of funding under the Incentive Grants formula when compared to the Targeted Grants formula. For example, New York would receive 9.65 percent of Incentive Grants funding compared to 12.65 percent of Targeted Grants funds and California's share of Incentive Grants funding is 13.72 percent compared to 15.7 percent of Targeted Grants.

The "effort" factor also could adversely affect States experiencing a local recession, which may have to reduce education spending in response to declining local tax revenues. A further decline in Title I support—as would occur under the Incentive Grants formula—would only exacerbate the problem faced by local districts and schools.

The "equity" factor, which produces highly variable patterns of gains and losses among States, suffers from flaws that seriously undermine its validity. These include the absence of any adjustment for cost-of-living variations among LEAs and reliance on a single measure of equalization.

Finally, the Education Finance Incentive Grant program does not provide a significant incentive for States to increase education funding or improve the equity of their funding systems. Even the $11.7 billion currently spent on Title I LEA Grants contributes only about 3 percent of national spending on elementary and secondary education.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

POVERTY DATA FOR FISCAL YEAR 2003 TITLE I ALLOCATIONS

Question. Since fiscal year 1997, Elementary and Secondary Education Act Title I funds have been allocated on the basis of estimates of school-aged children from poor families provided by the Census Bureau's Small Area Income and Poverty Estimates program, with updates every two years. Until the 2000 Census became available, Mississippi's poor student number was underestimated and using that method would have decreased the amount of Title I money for our State.

For 2003, the Department has a choice of using these updates, or school district population estimates from the 2000 Census. Which source of data do you plan to use for fiscal year 2003?

Answer. In determining Title I school district allocations for fiscal year 2003 (SY 2003–04), the Department will use the model-based poverty estimates provided by the Census Bureau. These estimates reflect sample data from the 2000 Census, which looks at income year 1999, and 1999 estimates provided through the Bureau's Small Area Income and Poverty Estimates (SAIPE) program.

We believe that the updated poverty estimates produced through the SAIPE model provide a more valid measure of school district poverty levels than the Census 2000 data and a more reliable basis for determining Title I allocations. These estimates factor in other, more up-to-date poverty measures such as Federal tax return and Food Stamp data, and address problems in the Census 2000 school district estimates resulting from sampling error.

Question. Are there significant differences in State shares using these two population data sources?

Answer. Overall, the total poverty count from the SAIPE model-based estimates is about 2.5 percent greater than the counts from the 2000 Census. Both sources produce State shares that are very similar for most States. For example, South Carolina's State share of the total 5–17 poverty with the 2000 Census is 1.54 percent, compared to 1.48 percent with the SAIPE model-based estimates. This translates to a 3.9 percent difference in South Carolina's State share when comparing the two. Over half of the States have State share differences less than 4 percent and three-fourths of the States have differences less than 7 percent. Only 6 States (Kansas, Idaho, Delaware, Maine, Massachusetts, and South Dakota) have State share differences over 10 percent. Massachusetts has the most significant difference

in State shares, with 1.45 percent of the total 5–17 poverty count with the 2000 Census and 1.84 percent of the total 5–17 poverty count with the SAIPE estimates (a 26.6 percent difference in State share).

NO CHILD LEFT BEHIND PROVISION FOR ANNUAL UPDATES ON CHILDREN IN POOR FAMILIES

Question. Finally, the No Child Left Behind Act allows for the use of annually updated data on children in poor families, rather than every second year—when do you expect to begin implementing this provision?

Answer. We plan to use annually updated model-based poverty estimates of children ages 5 through 17 by school district beginning with the fiscal year 2004 (SY 2004–05) allocations. Fiscal year 2003 is the final year for which we are using data updated on a biennial basis.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you all very much. The subcommittee will stand in recess to reconvene at 9 a.m., Tuesday, April 8, in room SD–192. At that time we will hear testimony from the Honorable Elias Zerhouni, Director, National Institutes of Health.

[Whereupon, at 9:51 a.m., Thursday, March 27, the subcommittee was recessed, to reconvene at 9 a.m., Tuesday, April 8.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2004

TUESDAY, APRIL 8, 2003

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Cochran, Harkin, and Murray.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF ELIAS ZERHOUNI, M.D., DIRECTOR

ACCOMPANIED BY:

DR. DUANE ALEXANDER, DIRECTOR, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

JAMES F. BATTEY, JR., M.D., PH.D., DIRECTOR, NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

WILLIAM R. BELDON, ACTING DEPUTY ASSISTANT SECRETARY FOR BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

FRANCIS S. COLLINS, M.D., PH.D., DIRECTOR, NATIONAL HUMAN GENOME RESEARCH INSTITUTE

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ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DR. PATRICIA A. GRADY, DIRECTOR, NATIONAL INSTITUTE OF NURSING RESEARCH

DR. JUDITH H. GREENBERG, ACTING DIRECTOR, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

GLEN R. HANSON, PH.D., D.D.S., ACTING DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

RICHARD J. HODES, M.D. DIRECTOR, NATIONAL INSTITUTE ON AGING

THOMAS R. INSEL, M.D., DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

STEPHEN I. KATZ, M.D., PH.D., DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

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DONALD A.B. LINDBERG, M.D., DIRECTOR, NATIONAL LIBRARY OF MEDICINE
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JOHN RUFFIN, PH.D., DIRECTOR, NATIONAL CENTER ON MINORITY HEALTH AND HEALTH DISPARITIES
DR. PAUL A. SIEVING, DIRECTOR, NATIONAL EYE INSTITUTE
ALLEN M. SPIEGEL, M.D., DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
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JACK WHITESCARVER, PH.D., DIRECTOR, OFFICE OF AIDS RESEARCH

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The Appropriations Subcommittee on Labor, Health and Human Services, and Education will proceed.

Dr. Zerhouni, we now turn to this portion of the hearing on the National Institutes of Health.

Dr. Gerberding, we thank you for your participation. If you would like to be a director of the NIH or one of the institutes, you may stay.

If you choose to retain your current position at CDC, you are free to excuse yourself. Thank you very much for joining us.

Dr. GERBERDING. Thank you. I think I will keep to my present job.

Dr. ZERHOUNI. We would not mind having her as a director at NIH.

Dr. GERBERDING. Thank you.

Senator SPECTER. Dr. Zerhouni, we have already introduced you with your impressive background and credentials coming from Algiers at a young age. We thank you for the work you are doing at NIH. It is good to hear that you were in Mississippi with Senator Cochran. Thank you for coming to Pennsylvania to a very interesting forum we had a few months ago at the University of Pennsylvania. And now we look forward to your testimony.

SUMMARY STATEMENT OF DR. ELIAS ZERHOUNI

Dr. ZERHOUNI. Thank you, Senator Specter. And thank you, members of the committee.

INTRODUCTION OF NEW INSTITUTE DIRECTORS

What I would like to do first and foremost is introduce to you four new directors of NIH who have joined us over the past year. Dr. Thomas Insel is the new Director of the National Institute of Mental Health. Thomas can say hi. Dr. Nora Volkow is going to assume the directorship of the National Institute of Drug Abuse. Dr. Rod Pettigrew is going to be, is the new Director of the National Institute of Bioimaging and Bioengineering. And T.K. Li is the new Director of the National Institute of Alcoholism and Alcohol Abuse.

To my right, I would like to introduce our new Deputy Director for NIH, Dr. Raynard Kington, who has replaced Dr. Ruth Kirschstein, who is now serving as the senior advisor to the directors, with us today as well and continues to help both Dr. Kington and I with her advice.

Senator SPECTER. Let me just pause for just a moment to thank Dr. Ruth Kirschstein for her outstanding service at NIH over many years, including serving as acting director. We salute you and are glad to see that you are still on board.

Dr. ZERHOUNI. Again, I would like to really extend our thanks to the full committee and to you, Mr. Chairman, and to you, Senator Harkin. We know that without your leadership, the doubling of NIH would not have occurred this year in the difficult economic and budgetary circumstances that we are facing. And we appreciate it very much.

RESEARCH PRIORITIES

I would like to quickly go over what NIH is planning to do with the doubling of the NIH budget and what our priorities are going to be. First and foremost, we want to make sure that the resources you have given us are invested with the best people and are invested on the best ideas that can promote the health of our people.

This is done in the context of, first of all, major priorities that continue to be priorities, but also evolving challenges. These evolving challenges are truly fundamental to the way biomedical research will need to be done in the future.

CHRONIC DISEASES

First and foremost, we have experienced over the past 40 years a tremendous shift in the landscape of disease in our country going from acute diseases that were very lethal to more chronic diseases. Seventy-five percent of the disease burden of the United States today is related to long-term chronic diseases. We have made great progress in cardiac diseases when we control acute myocardial infarction. But these patients are now surviving longer and have different kinds of problems.

AGING POPULATION

The second challenge is that of the aging population. And we need to tackle that proactively.

HEALTH DISPARITIES

The third is health disparities, as I mentioned before.

EMERGING DISEASES

The fourth, as you heard today, is emerging diseases. Not just infectious diseases, but also diseases that relate to the change in our environment, all conditions. For example, the rise in obesity and its implications on the incidence of diabetes in our country. Last, but not least, is the biodefense priorities, which we will continue to support.

STRATEGIC ROADMAP FOR NIH

Now to do so and to go forward, we wanted over the past year to work with all the directors of NIH and all the constituencies to define what we would call a strategic road map for NIH and how we will invest the resources you have placed in trust with us, and what are the priorities that we think will make the greatest difference in terms of advancing research, in terms of developing the best people, promoting the best ideas, and essentially translating them to real benefits. And there are three.

We will explore new pathways to discovery. And that is essentially to fully exploit the unprecedented opportunity of the genomic era. To us, this is the beginning, not the end, of an era. The genome is allowing us today to explore completely different ways of looking at disease than we had in the past.

Second, because of the scaling complexity of 21st century research, we understand now that the problems cannot be tackled by individual scientists alone. We need large multi-disciplinary teams that are going to work together to in fact do so.

Third, we need to re-engineer the clinical research enterprise of our country. We need to more quickly translate our discoveries into practice. And this will be a priority of the NIH in the future.

Last but not least, we are submitting to you a request for the fiscal year 2004 budget, which is a 2.6 percent change over the enacted 2003 level. When we worked—and Senator Specter and Senator Harkin and Senator Murray, I can tell you that we worked very, very hard, including myself and Dr. Gerberding and others to try to make sure that the impact on our programs in the new budget will be as limited as possible, in terms of critical mission areas. We did advocate internally, as you recommended in your statement.

Research will not be affected at the 2.6 percent level, but we will be able to maintain our research to the 7 percent level. Excluding biodefense, we will maintain a 4.3 percent level. And the number of grants will go 10,509.

At the bottom of the slide, you see why that is in 2004. And the reason is because many one-time expenditures that were related to building the infrastructure for biodefense, buildings and facilities that were needed in 2003 have been reinvested in the research portfolio in 2004. Now those are the main elements of the budget we are submitting. And as you said, Senator Specter, we are looking forward to your input in this process. And obviously, we will provide you with all the information that you may want us to provide you and answer all your questions in that regard.

But rest assured that we will and are committed and will be committed to make sure that the return on investment of the NIH continues to be the same it was in the past. Thank you very much.

[The statements follow:]

PREPARED STATEMENT OF DR. ELIAS ZERHOUNI

FISCAL YEAR 2004 PRESIDENT'S BUDGET REQUEST

Good morning, Mr. Chairman and members of the Committee. Let me begin by expressing my deepest appreciation for the generous and bipartisan support of the Congress, Secretary Thompson, President Bush, and the American people for the completion of the doubling of the NIH budget this year. I recognize and appreciate the extraordinary effort of this committee and, Mr. Chairman, your leadership as well as your efforts, Senator Harkin—without which the doubling would not have occurred. I thank you for it.

I also want to assure you that NIH fully understands and embraces its role as the steward of our Nation's investment in medical discovery. We must ensure that these precious resources are used wisely and lead to tangible benefits that touch the lives of everyone.

The year 2003 is truly a pivotal year for medical research. It is the year when we celebrate the 50th anniversary of the discovery of the structure of DNA and its direct consequence—the completed sequence of the Human Genome. We have witnessed nothing short of a revolution in science over the past 5 years. Some may see this year as the grand finale. I think of it more as the overture. As the 21st century begins to unfold, we are poised to make quantum leaps in our knowledge about how to improve people's health.

In my testimony, I will demonstrate what health benefits have resulted from the Nation's longstanding investment in the NIH, along with some of our most recent advances. Finally, I will outline emerging priorities and NIH's plans for responding to the health challenges before us.

THE NIH TRADITION

NIH-led progress in medical research is changing the landscape of disease. For example, NIH research led to a major reduction in mortality related to coronary heart disease and stroke. NIH contributed to this decline in a number of ways. First, we identified cardiovascular risk factors and the importance of behavior modification, such as smoking cessation, dietary changes, and exercise, to reduce risk and improve cardiovascular health. Second, we supported the basic science that led to the development of pharmaceuticals to control hypertension and high cholesterol levels. NIH-funded research also led to strategies as simple and inexpensive as taking aspirin to prevent heart disease and stroke, and life-saving procedures such as angioplasty and coronary artery bypass grafting. We also continue to evaluate best therapeutic strategies in medical practice, as in the recent ALLHAT trial (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial) that showed that hypertension can be effectively managed with an initial choice of an inexpensive drug. Were it not for these advances and others, the expected death toll from coronary heart disease would have been over 1,300,000 in 2000 as compared to the actual death toll of 514,000.

Progress has been equally remarkable for Hepatitis B (HBV) and Hepatitis C (HCV) infections. New cases of these infections are on the decline, in part, because of improved vaccines and the reduced risk of infection from blood transfusion—both outcomes of NIH-funded research. Because of changes in the criteria for donor recruitment and new and improved approaches to testing blood, the risk of infection through transfusion has been virtually eliminated.

The ability to screen for HIV infection—made possible by NIH research serves as an important target for both prevention and treatment of AIDS. The mortality rate of this devastating disease is now one fifth of what it would have been without research on the fundamental biology of the HIV virus. Research on behavioral interventions to prevent HIV infection and improve its treatment also contributed to better control of the spread of this disease in our country.

One more dramatic example can be found in the development of the Haemophilus Influenza B vaccine. The results of this NIH research have led to a virtual elimination of this disease in our country and, the disease is in the process of being elimi-

nated worldwide. In the not too distant past, the complications of Hib made this disease the leading cause of acquired mental retardation in infants and children.

NEW CHALLENGES AND STRATEGIES

Due in part to research advances; the burden of disease is now shifting from more acute and lethal forms of disease to chronic illness. Our success in conditions like myocardial infarction and infectious diseases is leading to better survival rates. As the result of such prolonged survival and the aging of the population, the incidence of chronic and long-term diseases, such as congestive heart failure, cancer, Alzheimer's disease, Parkinson's Disease, diabetes, and obesity, among others, is increasing.

For example, although we have witnessed reductions in acute coronary heart disease, the burden of congestive heart failure has increased during the last 30 years of the 20th century. As another case in point, more people are living with cancer, as therapies transform this once acutely fatal disease into a more chronic and manageable condition.

Furthermore, rapid changes in our environment and lifestyle lead to disequilibrium between our genetic make-up and our ability to adapt to these changes. The most dramatic recent example is the rise in the incidence of obesity, due in part to the greatly increased availability of food and reduced daily physical energy requirements.

It is imperative that we develop more comprehensive strategies to address such emerging challenges. In all likelihood, these strategies will require a better understanding of: (1) the series of molecular events that lead to disease in the hope of affecting its course before the disease develops, so-called Molecular Prevention; (2) the interactions between genes, the environment, and lifestyle as they relate to the etiology and progression of disease; ways of delaying the onset of the disease and/or ways to reduce the severity of its course and its impact on quality of life.

All of these strategies will need to be explored simultaneously and it is this systematic approach, from most basic to applied research, that will produce much needed results. Several important examples of these strategies have already proved their value.

For example, a major cause of blindness, age-related macular degeneration (AMD), currently affects 1.75 million Americans. They have advanced degeneration in at least one eye. Over 7 million individuals are at substantial risk of developing AMD. Its prevalence increases dramatically with age; for more than 15 percent of white females over 80 years of age have AMD. By the year 2020, the number of people with AMD will increase by 50 percent to 2.95 million.

NIH is engaged in a major research program to understand the predisposing factors, the clinical course, and the prognostic factors of AMD. Researchers found that giving high levels of antioxidants and zinc reduce the risk of developing advanced AMD by about 25 percent. These nutrients also reduce the risk of advanced AMD-induced vision loss by about 19 percent. These findings may help people who are at high risk of developing advanced AMD keep their vision. Over the next five years, 329,000 people in the United States (66,000 per year) could be saved from advanced AMD. More remains to be done. We need to spread the word to change practices, and we need to continue work to identify the genes that control the risk of this devastating disease as well as to develop more interventions to prevent or delay the onset of blindness.

In another example, many doctors today who are treating patients with rheumatoid arthritis remember all too well how challenging treatment was not so long ago. In the early 1980s, treatment was initiated in what was known as a therapeutic pyramid. Patients would first be given a course of aspirin or another nonsteroidal anti-inflammatory drug (NSAID), and would be followed to see if erosions occurred in the bone. If erosions did occur or if the patients did not respond to the NSAIDs, the next course was anti-rheumatic drugs that were added one-by-one as the disease progressed. Sadly, the disease-modifying therapy was initiated only after the patient was already on the road to disability. The root causes of the disease were not known, but the discovery, originally made through cancer research, of the role of Tumor Necrosis Factor (TNF), a naturally occurring protein in the body that mediates inflammation, dramatically changed the treatment landscape. By specifically targeting this protein with customised antibodies, entirely new drugs were developed and approved for the treatment of rheumatoid arthritis, including etanercept and infliximab. These were the first biological-response modifying antibody drugs that behave as antagonists—meaning that they work by specifically blocking the action and decreasing the availability of TNF.

These new-targeted therapies showed substantial effectiveness in people with rheumatoid arthritis who had not previously responded to other treatments. The treatments are generally well tolerated, although some concerns have been raised recently about the long-term effects of these agents. Other studies reported that infliximab and methotrexate used in combination not only reduced the symptoms of rheumatoid arthritis, but also halted the progression of joint damage when compared to the use of previous forms of therapy. Scientists involved in this study observed that in the last 2 years, aheumatoid arthritis research has moved further than in the previous 30 years, and that a wealth of new treatments is now available that have the potential to prevent and heal structural damage to the joints of people with this debilitating disease.

THE NEED FOR A STRATEGIC ROADMAP

The change in the landscape of disease requires us to adopt new approaches and accelerate the pace of our discoveries. The need has never been so pressing, the opportunities have never been greater, and challenges have never been more daunting. The NIH must simetaneously learn from the past, act in the present, and plan for the future. It must institute the changes necessary to improve the health of the American people. We need to proactively define enabling initiatives—how best to advance science as well as what science to advance. We need to map the terrain and over the past nine months we have been engaged in just such an effort.

Soon after I arrived at NIH, I convened a series of meetings to develop a "Roadmap." My goal was to develop a short list of the most compelling initiatives that the NIH should pursue that would make the biggest impact on biomedical research.

This assessment was needed because powerful and unifying concepts of biology are emerging that hold the potential to lead to rapid progress. For example, in the past, cancer research was considered vastly different than heart or brain research. Today, with recent discoveries in molecular and cell biology, we know that biological systems obey common laws and follow similar pathways in both health and disease. Efforts to fully understand these complex molecular events are beyond the reach of any one laboratory or group of investigators. As we begin to decipher the tidal wave of knowledge we have amassed, the scope, the scale, and the complexity of 21st century science will require us to devise even newer ways to explore biology for the sake of improving health.

Three major themes emerged from these Roadmap meetings. First, we must uncover new pathways to scientific discovery. For example, we must develop a comprehensive understanding of the building blocks of the body's cells and tissues and how complex biological systems operate. Also, structural biology will provide vital information about the proteins that make up the human body. Molecular libraries will give us new tools and targets for effective therapies. Overall, these examples, plus nanotechnology, computational biology and bioinformatics and molecular imaging will provide the foundation upon which new treatments, diagnostics and prevention strategies will emerge.

The second theme that emerged from our consultations is the changing dynamics of the research teams of the future. Because of the complexity and scope of today's scientific problems, traditional "mentor-apprentice" models must be replaced by integrated teams of specialists from numerous disciplines that were considered unrelated in the past. Imaging research, for example, requires cell biologists, computer programmers, radiologists, and physicists to work collaboratively on new diagnostics and treatments.

The third theme that was voiced again and again by researchers is the need to re-engineer the national clinical research enterprise for optimal translation of our discoveries into clinical reality. The list of what is needed is long—it includes supporting multidisciplinary clinical research training career paths, introducing innovations in trial design, stimulating translational research, building clinical resources like tissue banks, developing large clinical research networks, and reducing regulatory hurdles. We must explore a standard clinical research informatics strategy, which will permit the formation of nation-wide "communities" of clinical researchers made up of academic researchers, qualified community physicians, and patient groups.

Our vision is to make sure that our citizens benefit from a vibrant clinical research system—a system that will allow us to more efficiently translate our breakthroughs in basic research with the goal of improving health.

The three thematic areas that I just described, that is, new pathways to discovery, multidisciplinary teams, and reengineering the clinical research enterprise, focus on technologies and systems that will enable researchers today and in the future to not only solve problems more quickly, but also to ask questions that we have not been

able to ask before—questions so complex that without the aid of these efforts they would be impossible to address.

Efforts to understand the building blocks of the body's cells and tissues and to understand how complex biological systems work can lead directly to new approaches to improving health or preventing disease. A recently discovered biological phenomenon called RNAi—or RNA interference—has led to the development of a new and potent research tool, which is being used to identify the function of specific genes in normal biological and disease processes.

A recent study, co-funded by NIH, used RNAi to identify genes involved in the regulation of fat metabolism in the roundworm experimental model in an effort to better understand obesity. One at a time, each of the 17,000 genes of the round worm was turned off using this novel method. Researchers found that inhibition of 305 genes decreased body fat, whereas inhibition of 112 genes increased fat storage. With this information, researchers identified new genes involved in fat metabolism, genes common in many organisms, including humans. These genes now give researchers multiple new opportunities for understanding obesity and new targets for the development of therapies. This is just one example of how these new approaches are beginning to transform medical research.

Finally and importantly, the NIH must communicate our research results both to the lay public and health professionals. NIH works in partnership with many different organizations to communicate scientific results and health information to the medical research community, health care providers, patients, the media and the general public across the nation. We conduct our education and outreach efforts in collaboration with other federal agencies, state agencies, private sector organizations and national health care organizations. We have made progress in this area. For example, the NIH Web site is now the most accessed of all government health and science web sites. This aspect of our mission will continue to be a priority for NIH.

BIODEFENSE

Civilian biodefense research has become a new core priority at NIH and a prominent component of our budget. Over the last year and a half, we responded to the most urgent needs of biodefense, namely the development of countermeasures such as vaccines, therapeutics, and diagnostic tests. These will allow us to respond to and control the intentional or unintentional release of agents of terrorism that affect human health, including infectious disease and microbial toxins. We are also now systematically reviewing our portfolio of biodefense research to include radiation and chemical exposures, and mental health preparedness research. Biodefense research will be the topic of a separate hearing.

Mr. Chairman, I am pleased to present the President's fiscal year 2004 request for the National Institutes of Health of $27,663 million for the programs of NIH that fall under the purview of this Committee. This level will allow us to support our highest research priorities and continue the momentum we gained during the historic doubling of the NIH budget. In large part this is possible because of the very significant amount of one-time costs supported in fiscal year 2003 that will not be required in fiscal year 2004. Once these have been taken into account, NIH will be able to increase the amount available for research by 7.5 percent. Even after excluding increases for the Administration's highest priority—homeland defense—the research components of the NIH budget will still increase by 4.3 percent. The request will allow us to support the highest number of new and competing grants in history—10,509 new and competing grants. At this level, we will be able to continue to support approximately one-in-three of the research grant applications we receive. The final enacted fiscal year 2003 appropriation is very close to the President's request. In the coming weeks, NIH will work with appropriate staff to clarify discrepancies between the fiscal year 2003 request and the enacted level.

Special emphasis will be placed on areas of growing concern such as obesity and diabetes, the IDeA program, and the Best Pharmaceuticals for Children's Act. A total of $35 million is requested through the Director's Discretionary Fund to support our important Roadmap activities. As the fiscal year 2004 budget is developed, NIH will work with appropriate staff to clarify discrepancies.

In sum, the plans I have outlined here today are ambitious and rightly so. They rise to the many scientific opportunities and significant health challenges that lie before us. Once again, my thanks to you and the American public for your continued investment in biomedical research to improve the health of everyone.

BUILDINGS AND FACILITIES PROGRAM

The Buildings and Facilities (B&F) program supports the physical infrastructure required to carry out the in-house component of the biomedical research mission of the National Institutes of Health (NIH). The fiscal year 2004 Buildings and Facilities budget request supports efforts to sustain a robust, modern, safe and secure physical infrastructure for the conduct of basic and clinical research and research support across the spectrum of biologic systems and diseases.

The B&F budget request is the product of a deliberate, corporate facilities planning process both within the NIH and the Office of the Secretary, Assistant Secretary for Administration and Management, HHS. At the NIH, the Facilities Planning Advisory Committee (FPAC) oversees this process and provides advice to the NIH leadership and Director. The FPAC is also instrumental in adjusting priorities as necessary to deal with unanticipated public health challenges and changes in national priorities. The goal of the planning process is to optimally meet the changing facility needs of the NIH research programs in the Washington, D.C., region and across the NIH field stations with a mix of owned and leased facilities. The fiscal year 2004 Buildings and Facilities (B&F) budget request supports the NIH's research infrastructure priorities. The request includes projects and programs to responsibly manage the repair and upkeep of the existing physical infrastructure, and to maintain our facilities at an optimal operating standard to meet mission as well as safety and regulatory requirements.

The NIH appreciates the support from Congress in fiscal year 2003 for NIH's Physical Security, Biodefense facilities, and the final phase of the construction of the Mark O. Hatfield Clinical Research Center.

The fiscal year 2004 request maintains responsible funding support for the ongoing safety, renovation and repair, and related projects that are vital to proper stewardship of the entire portfolio of real property assets and continues the functional integration of the clinical research components of the existing Building 10 with the new Mark O. Hatfield Clinical Research Center (CRC).

The fiscal year 2004 B&F budget request is organized among three broad Program Activities: Essential Safety and Regulatory Compliance, Repairs and Improvements, and Renovations. The fiscal year 2004 request provides funds for specific projects in each of the program areas. The projects and programs enumerated are the end result of the aforementioned NIH Strategic Facilities Planning process and are the NIH's capital facility priorities for fiscal year 2004.

FISCAL YEAR 2004 BUDGET SUMMARY

The fiscal year 2004 budget request for Buildings and Facilities is $80 million. The B&F request includes a total of $14 million for Essential Safety and Regulatory Compliance programs composed of $2 million for the phased removal of asbestos from NIH buildings; $5 million for the continuing upgrade of fire and life safety deficiencies of NIH buildings; $1.5 million to systematically remove existing barriers to persons with disabilities from the interior of NIH buildings; $0.5 million to address indoor air quality concerns and requirements at NIH facilities; and $5 million for the continued support of the rehabilitation of animal research facilities. In addition, the fiscal year 2004 request includes $60.5 million in Repairs and Improvements for the continuing program of repairs, improvements, and maintenance that is the vital means of maintaining the complex research facilities infrastructure of the NIH. Finally, the request includes $5.5 million in Renovations for the Building 10 Transition Program.

My colleagues and I will be happy to respond to any questions you may have.

PREPARED STATEMENT OF DR. DUANE ALEXANDER

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2004 President's budget request for the National Institute of Child Health and Human Development (NICHD). The fiscal year 2004 budget includes $1,245 million, an increase of $41 million over the fiscal year 2003 enacted level of $1,205 million comparable for transfers proposed in the President's request. The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2002 results to the goals in our fiscal year 2002 performance plan.

Forty years ago, the U.S. Congress charged the NICHD with a broad mandate. The Institute was asked to develop a research program to ensure that people are able to have children when they want them; that every child is born healthy; that

women suffer no adverse consequences from the reproductive processes; and that children experience healthy physical, cognitive, behavioral, and social development, reaching adulthood free of disease and disability, and able to lead productive lives.

We have made exceptional progress toward those goals during the last 40 years. Infant mortality has been cut by more than 70 percent, largely due to NICHD research that has lead to new ways to treat and prevent respiratory distress syndrome, to manage premature infants, and to reduce Sudden Infant Death Syndrome. Mental retardation in the United States has been significantly reduced because we have conquered and controlled some of its leading causes: Hemophilus influenza type b (Hib) meningitis, phenylketonuria (PKU), measles encephalitis, and jaundice. Infertility that deprived millions of couples from conceiving children can now be diagnosed and in many cases treated. Transmission of HIV infection from mother to baby has been reduced from 27 percent to less than 2 percent in the U.S. as a result of research showing the effectiveness of administering antiretroviral drugs to the mother during pregnancy and to the infant just after birth.

We look forward to building on 40 years of scientific achievements and we would like to share with you recent achievements that are improving the health of the American people.

PREMATURE BIRTH: NEW RESEARCH MAY REVERSE A TREND

The number of infants who are born prematurely is increasing. While infant mortality rates have decreased significantly in recent years, the number of premature low birth weight babies born has increased by 11 percent over the last two decades. The number of premature very low birth weight infants, weighing less than 1,500 grams, has increased by 24 percent. Research supported by the NICHD has helped many premature infants to survive. But these infants can develop neurological, respiratory, or other conditions causing life-long disabilities. Recently, NICHD scientists discovered that weekly injections of progesterone, a readily available hormone, can lower premature birth by more than one-third among women who are at risk of premature delivery. In this study, like many clinical studies, some of the women received the progesterone and some received a placebo injection. The results were so dramatic that the scientists halted the study and administered progesterone to all women enrolled in the study.

ORAL CONTRACEPTIVES AND BREAST CANCER: NO ASSOCIATION

The NICHD research has also provided reassuring evidence to women and their physicians who may be concerned about a possible relationship between oral contraceptive use and breast cancer. About 80 percent of U.S. women born since 1945 have used oral contraceptives. Conflicting studies had caused concern about the possible effect of oral contraceptive use on breast cancer risk. The NICHD's Women's Contraceptive and Reproductive Experiences Study found that women between the ages of 35 and 64 who took oral contraceptives at some point in their lives were no more likely to develop breast cancer than other women the same age who never took oral contraceptives. Many women who took oral contraceptives during their reproductive years are now reaching the ages of greatest breast cancer risk. This study should resolve the long-standing concern that oral contraceptive use might be associated with an increased risk of breast cancer in later life.

VASECTOMY AND PROSTATE CANCER: NO ASSOCIATION

Another study supported by the NICHD answered an important question for men who have had vasectomies. About one out of six American men over the age of 35 has had a vasectomy. Some studies conducted in the United States in the early 1990s reported a moderately increased risk of prostate cancer among men who underwent vasectomy. Other studies found no such risk. Because of this conflicting evidence, many urologists have increased prostate cancer screening of men who had vasectomies and have discouraged vasectomies in men with a family history of prostate cancer. The NICHD study found that men who had a vasectomy were no more likely to develop prostate cancer than those who had not had a vasectomy. The study also found that men who had vasectomies as long as 25 years ago did not have an increased risk of prostate cancer. These results should reassure men who have had or who are considering a vasectomy.

STROKE PATIENTS IMPROVE FUNCTION OF IMPAIRED LIMB

The results of other NICHD-supported research provide encouraging news to some stroke victims. Until recently, therapy for stroke victims often involved teaching patients to strengthen their less impaired limb for several weeks after a stroke. The

prevailing view among rehabilitation professionals was that patients' motor ability reached a plateau at about six months after a stroke. They believed that additional therapy would provide little if any additional benefit. But new research has shown that the use of the impaired limb can improve significantly a year or more after a stroke. Using "Constraint Induced Therapy," researchers showed that constraining the good or less affected limb for 10 days can help restore a great deal of mobility to the impaired limb.

TRAUMATIC BRAIN INJURY NETWORK FOR BETTER TREATMENTS

Traumatic brain injury is one of the leading causes of death and disability in children and adults. An estimated two million head injuries occur in the United States each year. As a result of advances in emergency medicine at the accident scene and the hospital, many TBI victims are living longer. However, many will live with persistent physical, cognitive, behavioral and social deficits that compromise their quality of life. Research over the last two decades has demonstrated that not all neurologic damage occurs at the moment of injury, but evolves over the minutes, hours, and days after an accident. Research also has dramatically improved the immediate care, follow-on care, and rehabilitative process for TBI patients. Yet there are many unanswered questions about the underlying damage and the reasons for reduced functioning associated with TBI. In addition, to determine the most appropriate therapies for children and young adults with TBI, multiple sites are needed to evaluate various interventions with many patients. To address this need, the NICHD recently established the Traumatic Brain Injury Clinical Trials Network. The Network will evaluate medical, rehabilitative, and educational interventions to identify which ones most effectively improve the long-term outcomes of TBI patients.

NEW FRAGILE X CENTERS WILL DEVELOP TREATMENT OPTIONS

Fragile X syndrome is the most common genetically-inherited form of mental retardation currently known. The condition occurs in every 1 out of 2,000 males and in 1 in 4,000 females. The syndrome is caused by a mutation in a specific gene (FMR1) on the X chromosome. In its fully-mutated form, the FMR1 gene interferes with normal development. In a partially mutated (premutation) form, the FMR1 gene can cause fragile X syndrome in the children of a carrier (a person who has the premutation gene). Until recently, however, the premutation form was not thought to cause symptoms in carriers. Scientists have now identified a subgroup of premutation FMR1 carriers with symptoms that appear to be associated with the gene. Symptoms included mild cognitive and emotional problems and, in female carriers, premature menopause. In older male carriers, the premutation gene is associated with a neurological syndrome. Identifying a genetic basis could be a first step toward accurate diagnosis and, possibly, development of new treatments for these often overlooked symptoms. In addition, to develop improved diagnostic techniques and treatment options, the NICHD will begin funding three new Fragile X research centers in fiscal year 2003. Each center will call upon the combined expertise of several researchers working in diverse fields to investigate different aspects of the disorder. The new Fragile X Research Centers will study issues such as how the fragile X affects the developing brain and nervous system, how the disorder progresses throughout an individual's life span, and effective treatments that can improve the behavior and mental functioning of people with fragile X syndrome.

STRATEGIC ALLIANCES WITH MINORITY GROUPS TO REDUCE SIDS

Less than ten years ago, the NICHD initiated a campaign urging parents and care takers to place infants on their backs to sleep to reduce the risk of Sudden Infant Death Syndrome (SIDS). Since that time, the SIDS rate in the U.S. has declined by more than 50 percent. This dramatic decline represents a significant public health achievement because the SIDS rates had remained tenaciously steady prior to the NICHD campaign. Although the SIDS rates have declined in all populations since the campaign began, the SIDS rate among African American infants remains double that of white infants. Among Alaska Natives and many American Indian tribes, the rates are higher still. To begin closing this gap, the NICHD has formed strategic alliances with the Alpha Kappa Alpha sorority, The National Coalition of 100 Black Women, and The Women in the NAACP. In collaboration with these organizations, the NICHD has planned and will support a series of "summit" meetings in three U.S. cities with high rates of African American SIDS deaths. These summits will enlist the resources of faith-based and community organizations, public health officials, and service organizations to help establish an infrastructure that will provide information, material, and support for reducing SIDS among African American infants. Each organization will take the lead in organizing one of the sum-

mit meetings and will continue to serve as the catalyst for SIDS risk reduction activity in that city and its surrounding region.

The NICHD has also initiated a project with American Indian and Alaska Native groups to reduce SIDS and infant mortality in these populations. At NICHD-sponsored meetings in Minneapolis, MN and Rapid City, SD, representatives of Tribal Chairman's Health Boards and Alaska Native health organizations provided the NICHD with a blueprint to support the activities of community health workers involved in SIDS risk reduction education. The NICHD will develop and disseminate the materials for this effort during the current year.

TESTING DRUGS TO IMPROVE HEALTH OF CHILDREN AND PREGNANT WOMEN

In fiscal year 2004, the NICHD will continue to invest in research and programs that benefit the American people. One such investment is the fulfillment of the Best Pharmaceuticals for Children Act (BPCA). The immature physiology of children means that drugs approved to prevent or treat illness in adults may have different effects in younger patients, requiring children's physicians to prescribe different doses and make other adjustments in drug therapies. However, for approximately seventy-five percent of the pharmaceuticals approved by the Food and Drug Administration (FDA) for adults, there are inadequate safety and efficacy data to allow approval for pediatric uses, or to guide physicians in prescribing these drugs for children. The BPCA, signed into law in January 2002, directs the NIH to issue contracts to test in children off-patent prescription drugs already approved for adults. Working with the FDA and other experts, the NICHD identified a priority list of drugs to be tested through the Institute's Pediatric Pharmacology Research Units (PPRUs) and at other sites. The fiscal year 2004 budget request includes an increase of $25 million, across all of the NIH Institutes and Centers (ICs), for these studies.

Drugs prescribed to pregnant women are also a concern. Although nearly two-thirds of all pregnant women take at least four to five drugs during pregnancy and labor, the effects of these prescribed drugs on a pregnant woman and her fetus remain largely unstudied. In addition, little is known about how pregnancy-related changes in cardiac output, blood volume, intestinal absorption, and kidney function may influence drug absorption, distribution, utilization, and elimination. Therefore, the NICHD will establish a new network of Obstetric-fetal Pharmacology Research Units that will allow investigators to conduct key pharmacologic studies of drug disposition and effect during normal and abnormal pregnancies.

EXPANSION OF NEWBORN SCREENING THROUGH MICROARRAY TECHNOLOGY

At present, all states routinely screen all newborns for only two disorders: phenylketonuria (PKU) and congenital hypothyroidism. These are conditions for which effective treatments are available. In addition, most states screen for a mix of 1 to 15 other disorders, but some commercially available tests can screen for up to 50 conditions. A Secretarial-level panel and the American Academy of Pediatrics have recommended that an expanded and standardized approach to newborn screening be developed. To address this need, the NICHD proposes to apply the knowledge and techniques garnered from the Human Genome Project. Using cord blood and microarray technology, there is the potential to identify disease genes at birth for more than 200 single gene defects associated with mental retardation, nearly 100 associated with immunodeficiency disorders, approximately 10 causes of muscular dystrophy, and cystic fibrosis. Although treatments are available for many of these conditions, effective study of potential new treatments for others requires a population who has not yet developed symptons of the condition. Screening of newborn infants can provide this population. This testing could be done in one procedure so that economies of scale and simplicity may overcome one of the major obstacles to widespread acceptance of expanded newborn screening: cost.

The NICHD will collaborate with several other ICs, research institutions, and industry to develop the appropriate microarray chip and associated technology for mass screening and pilot test the new screening technology. This approach would maximize the use of newborn screening for preventive purposes. Moreover, by developing this translational research, NICHD will fulfill one of the objectives of the NIH road map activities.

Mr. Chairman, I will be happy to provide answers to any questions you have.

PREPARED STATEMENT OF DR. JAMES F. BATTEY, JR.

Mr. Chairman and Members of the Committee, I am pleased to present the President's budget request for the National Institute on Deafness and Other Communica-

tion Disorders (NIDCD). The fiscal year 2004 budget includes $380,377,000, which reflects an increase of $10,190,000 over the fiscal year 2003 enacted level of $370,187,000 comparable for transfers proposed in the President's request. Disorders of human communication exact a significant economic, social, and personal cost for many individuals. The NIDCD supports research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech, and language. Results of NIDCD's research investment will foster the development of more precise diagnostic techniques, novel intervention and prevention strategies, and more effective treatment methods for the millions of Americans with communication disorders. My testimony will highlight some examples of research progress in human communication sciences.

Cochlear Implants.—If Ludwig van Beethoven were able to reverse his deafness and regain his hearing again as he reached the climax of his career as a composer, would the world have been blessed with even more of his music? Scientific technology has advanced significantly since the 18th century, and assistive hearing devices are now able to restore sound perception to deaf individuals. One such device, the cochlear implant, has provided hope to thousands of deaf individuals worldwide. A cochlear implant converts sound into electrical impulses, bypassing the damaged sensory hair cells that detect sound, stimulating the auditory nerve directly and restoring sound perception. According to the Food and Drug Administration 2002 data, approximately 59,000 people worldwide have received cochlear implants. In the U.S., about 13,000 adults and nearly 10,000 children have received them. With over 30 years of NIH research investment, the cochlear implant has evolved from an experimental device to a commercially available treatment to assist those who are profoundly deaf or severely hearing impaired.

Hereditary Deafness Gene Discovery.—Within the last seven years, over 70 different genes for hearing loss that is not associated with other inherited characteristics (nonsyndromic hereditary hearing impairment) have been mapped and over 25 identified. In addition, several genes essential for normal auditory development and/or function have been identified using mouse models. Recently, scientists have discovered a new gene of unknown function, TMC1, in which mutations cause deafness. NIDCD intramural scientists have identified a mutation in the mouse Tmc1 gene which causes similar types of dominant and recessive hearing loss found in large human family studies. In mice, mutations in the Tmc1 gene causes defects in the function of the specialized sensory hair cells of the inner ear. Hair cells detect and convert the physical stimulus of sound into electrical impulses sent to the brain via the auditory nerve. This research contributes to new models for studying specific forms of human deafness.

Sensory Stereocilia Renewal Aid Recovery to Hearing Loss.—Stereocilia, or hair cell bundles, are fine projections in the inner ear that vibrate when stimulated by sound. The movement of the stereocilia activates a molecular pathway that generates an electrical signal from the auditory nerve to the brain, which is interpreted to be sound. Stereocilia are located in the surface of the inner ear and are supported by a rigid and dense core of filaments. Until recently, this core was thought of as a stable structure whose sole function was to serve as rigid supports for changes in the mechanical property of the hair cells. NIDCD intramural scientists have discovered that there is a continuous renewal of the stereocilia core every 48 hours. This process occurs in the mature bundles during recovery from temporary noise-induced hearing loss and suggests that the stereocilia core structure plays an unforeseen role in this recovery process. Such a renewal mechanism could also provide more information on the molecular basis of genetic, environmental, and age-related inner ear disorders that involve malformation or disruption of stereocilia.

Motor Protein Facilitates the Speed of Sound.—One important component in the mechanical transmission of sound from the ear to the brain is Myosin-1C, a major motor protein involved in the movement of the stereocilia in the inner ear. It is hypothesized that motor proteins serve as the link between the stereocilia's membrane and cell core thereby changing the polarity of hair cells following sound vibration. NIDCD-supported scientists are in the process of deciphering how Myosin-1C works. Specifically, they used a chemical-genetic approach to inhibit Myocin-1C motor protein activity in mice by introducing a custom designed amino acid that alters the protein's function. The designer amino acid rendered the protein susceptible to a controllable inhibitor, thus allowing regulation of the protein's motor function. These results demonstrate the importance of Myosin-1C in transmitting sound to the brain, allows observation of protein function in a controllable native environment and permits assessment of protein function in a biological process.

Antibiotic Controls the Vertigo of Ménière's Disease.—Ménière's disease is a distressing and often disabling disorder of inner ear function, characterized by spontaneous attacks of vertigo, fluctuating hearing loss, tinnitus and fullness in the ear.

When vertigo cannot be controlled by diet or medication, severing of a vestibular nerve from the affected ear usually controls vertigo while preserving hearing. NIDCD-supported scientists have demonstrated that a single injection of the antibiotic, gentamycin, through the eardrum into the middle ear space, is an alternative to surgery and is effective in diminishing vestibular response and in controlling vertigo in individuals with Ménière's disease. Experimental studies suggest that gentamycin reduces vestibular responsiveness, and hence, vertigo, by causing a toxic effect on the vestibular hair cells, the sensory receptors that detect head motion stimuli and orientation.

Odorant Receptors Help Mosquitoes Smell Their Prey.—The sense of smell (olfaction) plays an important role for blood-feeding female mosquitoes in finding a host. Mosquito-borne disease is a serious world health concern, and the mosquito is known to transmit a variety of deadly diseases, including malaria, West Nile virus, dengue and yellow fever. Host preference, especially to humans, in the female mosquito is a critical component of disease transmission. NIDCD-supported scientists are characterizing the genes that play a role in the function of the olfactory system of Anopheles gambiae and have identified odorant receptor-encoding genes selectively expressed in the olfactory organs of this malaria-transmitting mosquito. Blood-feeding and host preference selection involve only the female mosquito, so the scientists studied the expression of odorant receptor genes, AgOr, in the female mosquito's primary olfactory organ—its antennae. It was observed that AgOr1 is turned off in the olfactory tissue of the female mosquito 12 hours after a blood meal, which is consistent with decreased host-seeking behavior. These findings suggest that AgOr1 may detect an olfactory signal that is active in female mosquitoes before but not after a blood meal. Developing selective antagonists to AgOr1 may help to control the transmission of malaria and other mosquito-borne diseases, and may also represent a novel disease prevention approach that is based on an understanding of olfactory receptor genes. In addition, these findings may ultimately be useful in developing new repellants and attractants that are more effective, economical and ecologically friendly.

Discovery of an Amino Acid Taste Receptor.—Taste is responsible not only for attraction and repulsion to various foods but is also responsible for providing important information about the chemical environment. The basic taste qualities are sweet, sour, salty, bitter and umami (the taste of monosodium glutamate or the taste associated with protein-rich foods). A major challenge in taste research is identifying the various types of taste receptors on the tongue that respond to different structurally diverse compounds. Recently, scientists have identified a taste receptor dedicated to tasting amino acids, the building blocks of proteins that are involved in the biological processes in the body. It has been known that sweet-, bitter- and umami-tasting substances activate G-protein-coupled receptors in the tongue. NIDCD-supported scientists discovered that two subunits in the T1R receptor family, T1R1 and T1R3, can combine to form an amino acid receptor, T1R1+3, that responds to most of the 20 standard amino acids. Identification of an amino acid taste receptor provides a new tool to help scientists decode the molecular basis for detecting different taste qualities in mammals.

Do Stutterers Have Different Brains?—To study the brain activity patterns in the cortical speech-language areas of the brain of individuals who stutter, NIDCD-supported scientists performed brain imaging studies on two groups of adults; those with or without persistent developmental stuttering (PDS). Results of the analysis showed that differences in the speech-language areas of the brain are more common in adults with PDS, although no one anatomic feature accounted for the group differences. The major anatomic finding was that the size of the right and left planum temporale (PT) of the brain were significantly larger in the adults with PDS. The PT is important for higher order processing of language information. The results about the PT size and other findings, such as variations of infolding patterns of the brain, demonstrate that atypical size or shape of the speech-language area may put individuals at risk for stuttering.

Speech-Sound Disorders are Risk for Later Academic Impairments.—Children with speech-sound disorders often have difficulties in other areas of language as well. These disorders are characterized by the inability to use speech sounds that are normal for the individual's age and dialect. Speech-sound disorders involve language difficulty affecting an individual's ability to learn and organize speech sounds into a system of sound patterns. Poor awareness of speech skills and a weakness in vocal sound classification in verbal memory may put children of preschool age with speech-sound disorders at risk for later spelling difficulties. In a recent NIDCD-supported study, the spelling errors of children with history of speech-sound disorders were analyzed to predict the association between weaknesses in spoken language skill in early childhood and school-age spelling abilities. The findings of this study

support previous research indicating that children with early speech-sound disorders are at risk for later spelling difficulties. Evidence from studying these families raises the possibility of a common genetic cause for speech/language and written language disorders. Although the genetic cause for these disorders is not known, specific signs of the disorder suggest a male gender bias since brothers were also more likely to have the disorder than sisters. The findings of this study reveal that preschool children with speech-sound disorders are at risk for later spelling impairments even after productive speech disorders have resolved.

A Possible Gene for Childhood Language Disorders.—Children who fail to develop language normally (in the absence of factors such as neurological disorders, hearing impairments, or lack of adequate opportunity) have specific language impairment (SLI). SLI has a prevalence of approximately 7 percent in children entering school and is associated with later difficulties in learning to read. Research studies have consistently demonstrated that SLI clusters in families, suggesting that genetic factors may be an important cause of SLI. NIDCD-supported scientists are scanning the genome for the location of the gene suspected of causing SLI, by studying families where multiple members have with language/reading disorders. The study showed significant evidence of a link between a region of chromosome 13 and susceptibility to SLI. Further analysis also suggests two additional gene locations on chromosomes 2 and 17 that may play a role in SLI. In addition, mutations in the same region in chromosome 13 is implicated in autism, and some children with autism show language deficits that are very similar to SLI.

Mr. Chairman and Members of the Committee, these are just a few examples of NIDCD's research advances. I would be pleased to answer any questions you may have.

PREPARED STATEMENT OF DR. FRANCIS S. COLLINS

Mr. Chairman and Members of the Committee: Due in great part to the visionary leadership and commitment of Congress, this month the International Human Genome Project (HGP), led by the National Human Genome Research Institute (NHGRI) of the National Institutes of Health (NIH), will have accomplished all of its original goals, ahead of schedule and under budget. This historic achievement, in the month of the 50th anniversary of Watson and Crick's seminal publication of the structure of DNA, opens the genomic era of medicine. April will also witness the publication of a bold vision for the future of genomics research, developed by the NHGRI. This vision, the outcome of almost two years of intense discussions with hundreds of scientists and members of the public, has three major areas of focus: Genomics to Biology, Genomics to Health, and Genomics to Society.

Genomics to Biology.—The human genome sequence provides foundational information that allows development of a comprehensive catalog of all of the genome's components, determination of the function of all human genes, and deciphering of how genes and proteins work together in pathways and networks.

Genomics to Health.—Completion of the human genome sequence offers a unique opportunity to understand the role of genetic factors in health and disease, and to apply that understanding rapidly to prevention, diagnosis, and treatment. This opportunity will be realized through such genomics-based approaches as identification of genes and pathways and determining how they interact with environmental factors in health and disease, more precise prediction of disease susceptibility and drug response, early detection of illness, and development of entirely new therapeutic approaches.

Genomics to Society.—Just as the HGP has spawned new areas of research in basic biology and in health, it has created new opportunities in exploring societal issues. These include analysis of the impact of genomics on concepts of race, ethnicity, kinship, individual and group identity, health, disease, and "normality" for traits and behaviors, and defining policy options regarding the use of genomic information in both medical and non-medical settings.

NEW NHGRI INITIATIVES

The NHGRI has already begun several new initiatives, and is planning others, to meet the challenge of this new vision for the future of genomics. Below are examples of these cutting edge programs.

The Creation of a Human Haplotype Map

Multiple genetic and environmental factors influence many common diseases, such as diabetes, cancer, stroke, psychiatric disorders, heart disease, and arthritis; however, relatively little is known about the genetic basis of common diseases. The

NHGRI has begun to create a "haplotype map" of the human genome to enable scientists to find the genes that affect common diseases more quickly and efficiently. The power of this map stems from the fact that each DNA variation is not inherited independently; rather, sets of variations are inherited in blocks. The specific pattern of particular genetic variations in a block is called a haplotype. This new initiative, an international public/private partnership led and managed by NHGRI, will develop a catalog of haplotype blocks, the "HapMap." The HapMap will provide a new tool to identify genetic variations associated with disease risk or response to environmental factors, drugs, or vaccines. Ultimately, this powerful tool will lead to more complete understanding of, and improved treatments for, many common diseases.

The ENCODE Project: ENCyclopedia Of DNA Elements

To utilize fully the information that the human genome sequence contains, a comprehensive encyclopedia of all of its functional genetic elements is needed. The identity and precise location of all transcribed sequences, including both protein-coding and non-protein coding genes, with their structure, transcription start sites, polyadenylation sites, and alternative splicing variants must be determined. The identity of other functional elements encoded in the DNA sequence, including promoters, enhancers, and other transcriptional regulatory sequences, and determinants of chromosome structure and function, such as origins of replication and hot spots for recombination, also is needed. The NHGRI has developed a public research consortium to carry out a pilot project, focusing on a carefully chosen set of regions of the human genome, to compare existing and new methods for identifying functional genetic elements. This ENCyclopedia Of DNA Elements (ENCODE) consortium, which welcomes all academic, government, and private sector scientists interested in facilitating the comprehensive interpretation of the human genome, will greatly enhance use of the human genome sequence to understand the genetic basis of human health and to stimulate the development of new therapies to prevent and treat disease.

Chemical Genomics

One novel way that the NHGRI plans to pursue translating genomics to human health is the development and deployment to the biomedical research community of libraries of small organic compounds. This is a fundamentally new approach for research in the public sector, and will accelerate understanding of the function of the human genome and the development of new treatments. The NHGRI proposes to use the types of organic molecules in most marketed pharmaceuticals, "drug-like," or "small" molecules, as a core of this resource. In collaboration with other NIH institutes, the NHGRI is planning for a resource that includes: (a) large libraries of chemical compounds of appropriate structural diversity and properties; (b) assay development capacity; (c) robotic assay capacity, also termed high throughput screening (HTS); (d) medicinal chemistry capacity to transform "hits" identified by HTS into workable chemical probes; and (e) distribution capacity to disseminate the reagents to the biomedical research community efficiently.

Genome Technology Development

The NHGRI continues to invest in technology development that furthers the uses of genomics. Technical advances have caused the cost of sequencing to decline dramatically, from $10 to less than $0.09 per base pair, but this cost must decline even further for all to benefit from genomic advances. The NHGRI, along with many partners, will actively pursue the development of new technologies to sequence any individual's genome for $1,000 or less. Other areas of technology development are also ripe for expansion and the NHGRI plans to pursue them vigorously.

Studying the Genetic Basis of Health

Analytic methods to find genetic variants that contribute to disease can also help find genes and genetic variants that contribute to health. The NHGRI plans to support development of new tools and analytical methods to discover the genetic components of resistance to diseases, disorders, toxins, and drug reactions. By finding genetic variants that convey reduced susceptibility, researchers will better understand disease processes and how to slow, or even prevent, them. Promising approaches for identifying disease-resistant gene variants include studying people at high risk for a disease who do not develop it, relatives of people with disease who do not themselves have the disease, or individuals who reach extreme old age without serious illness.

RECENT SCIENTIFIC ADVANCES IN GENOMICS

Progress in Sequencing Model Organisms

From the Human Genome Project's outset, the NHGRI and its partners have included, among their research goals, mapping and sequencing the genomes of several non-human organisms, since they would be of great value in understanding the biological data encoded in the human DNA sequence and, thus, in combating human disease. Genomic sequences for a number of important organisms, beyond those initially identified by the HGP, have been determined. Primary among these is the laboratory mouse. In December 2002, an analysis of an advanced draft of the mouse genome was published and provided a key tool for interpreting the human sequence. The first assembly of the rat genome sequence was announced in the same month by the Rat Genome Sequencing Project. A peer review process now selects new genomes to sequence. To champion an organism, scientists write a "white paper" that presents arguments for prioritizing their proposed target for sequencing. After two rounds of white papers, this process determined the highest priority as: chicken, chimpanzee, cow, dog, a set of fifteen fungi, honeybee, sea urchin, and two protozoans. Sequencing of the chicken, chimpanzee, and honeybee has already begun.

ETHICAL, LEGAL AND SOCIAL IMPLICATIONS OF GENETIC RESEARCH

The NHGRI devotes five percent of its annual budget to research involving the ethical, legal and social implications (ELSI) of genetics and genomics. Below are examples of this program's important work.

Genetic Discrimination

Most Americans are optimistic about the use of genetic information to improve health, but many are also concerned that insurers and employers will misuse genetic information. These concerns deter participation in important biomedical research and the clinical use of genetic information. The NHGRI has supported research efforts to elucidate this issue. Such research has helped inform legislative activity; over 40 states have passed genetic nondiscrimination bills.

Reducing Health Disparities

The NHGRI recognizes the critical importance of ensuring that the potential of genomic research benefits all racial and ethnic groups. The NHGRI has taken steps to engage and empower minority communities in genomic research. The rewards of genomic research will be realized only with active participation of all racial and ethnic groups. An important area of genomic research is investigating how DNA sequence variation affects differing susceptibility to disease among various populations. The significant societal ramifications of this research also need attention. Genomic research affects all populations; thus, all groups need to set the research agenda and examine the broader issues it raises. The NHGRI has intensified its efforts to address health disparities by developing a strategic plan that identifies goals in areas such as research projects, information sharing, development of partnerships, and increasing diversity of the research workforce.

Effects of Gene Patents and Licenses on Genetic Testing and Research

The NHGRI continues to be concerned about the issues of gene patenting and licensing. To gain a better understanding of these issues, it has funded case studies and surveys to describe and analyze the effects of patents that award proprietary claims to the use of DNA sequences. The NHGRI held a roundtable discussion in December 2002 with outside experts in gene patenting to explore the ramifications on healthcare delivery and research of patenting and licensing genetic sequence data and single nucleotide polymorphisms. The NHGRI will utilize the insights provided at this roundtable to define further research to inform the policy process.

CONCLUSION

This year marks a very exciting transition in the field of genomics, with the full sequencing of the human genome marking the successful achievement of all of the HGP's original goals, and thus the advent of the genomics era. When Congress decided to fund the HGP it did so with the justifiable belief that this work would lead to improved health for all. The ability to accelerate the realization of this vision now lies before us. At the same time, we must be sure that all our citizens have access to these technological advances and that this information is not misused. It is our sincere belief that the newly created discipline of genomics will make a profound difference on the health and well being of the people of this world. We are profoundly grateful for the support the Congress has given to this program.

Mr. Chairman, I am pleased to present the President's budget request for the National Human Genome Research Institute. The fiscal year 2004 budget includes $478,072,000, an increase of $13,467,000 over the fiscal year 2003 enacted level of $464,605,000 comparable for transfers proposed in the President's request.

PREPARED STATEMENT OF DR. ANDREW C. VON ESCHENBACH

The early part of the 21st century promises to be a period of unprecedented progress in conquering our most debilitating diseases especially cancer. The nation's unwavering support of the biomedical research enterprise, in particular, the unified effort by this committee, all of Congress, and the President to double the NIH budget over the past five years, has positioned us to attack this devastating disease more effectively. Cancer affects nearly every family in America. In 2003, 1.4 million of our citizens will face a diagnosis of cancer—and over 560,000 of our citizens will die from their disease this year. Every day, 1,500 Americans lose their own battle with cancer. These are daunting statistics, and the aging of the baby boomer population and shifting demographics of America during the next 15–20 years represent enormous healthcare and economic challenges that we must begin to prepare for now.

But, there is reason for optimism! Our nation's investment in basic research has fueled the engine of discovery, thereby enabling unparalleled advances in illuminating the genetic changes and molecular mechanisms that ultimately produce cancer. The sequencing of the human genome and associated progress in new areas such as functional genomics, animal models of cancer, and proteomics, provide us with a clearer picture of the disturbances that cause cancer to develop and ravage the human body. For the first time, we have within our grasp the ability to design target-specific interventions to preempt this process. We must enrich these extraordinary advances in basic science with equally extraordinary efforts to develop new agents and technologies to actualize these interventions at key steps in cancer progression. We now understand that cancer is a process—a process with multiple opportunities to develop new, more effective interventions to prevent, detect and treat cancer.

To capitalize on this knowledge, we must significantly accelerate the pace of progress across the entire research continuum. The pathway begins with discovery of knowledge that underpins the development of new molecules and tools and ends with the delivery of diagnostics and therapeutics to patients. Discovery, development and delivery are interlinked, and it is crucial that we take the steps needed to ensure that all phases of the research enterprise are functioning optimally.

I believe that we stand at an "inflection point" in our nation's effort to conquer cancer. The research enterprise has delivered remarkable scientific achievements in biomedical research over the past decades, and we now are positioned to experience a rapid increase in the trajectory of this research. This affords us an unprecedented opportunity to harness strategically these achievements to confront the challenges of cancer today and tomorrow.

We now envision a time when the suffering and the death that are caused by cancer will be eliminated; and we believe that it is realistic to set ourselves a challenge goal to achieve this vision by the year 2015. I have presented the cancer research community with this challenge and am confident that they will achieve the goal. I want to be clear what we mean by "reduce suffering and death from cancer," and to explain why I believe that this vision is achievable.

We are not saying that all cancer will be cured or eliminated. What we are saying is that in this 12-year time-frame, many cancers will be cured, but many more will be transformed into chronic, manageable diseases that patients can live with—not die from. There is precedent for this paradigm shift. In a single generation, we made enormous strides in reducing deaths from coronary artery disease and converting this disorder into a condition that people live with and manage. Likewise, using our knowledge of the AIDS virus, molecular biology, and skills in developing target-based therapy, we have developed treatments for AIDS patients that both save lives and preserve quality of life. I think we can do the same for cancer.

This vision presents new challenges for the NCI and for everyone working to conquer this devastating disease. We will meet those challenges by further strengthening basic research, especially in advancing our understandings about the mechanisms of cancer progression. In parallel, we will intensify our focus on developing the clinical research and delivery systems needed to provide the promise of everything that science can provide to everyone in need.

I discovery, we will establish a national effort to "map" the critical events of the complex of integrated cancer disease pathways at the cellular level. This "systems biology approach" will allow us to dissect strategically the complex and redundant

reactions and interactions within cells, and will enhance our technical capabilities to identify molecular targets and create new therapies. We will also focus on the exploration of new technologies, in reas such as molecular imaging, proteomics and genomics, and nanotechnology. These new technologies offer the promise of developing new platforms to monitor cells, identifying intricate molecular changes, and delivering therapeutics to specific targets within the cell. The application of these advanced technologies is no longer a dream. Advances in positron emission tomography, coupled with new molecular imaging agents, now make functional monitoring possible, permitting clinicians to "visualize" the biologic progress of cancer. Scientists and engineers are working to achieve this goal through NCI's unique programs that foster the development of innovative technologies for cancer diagnosis and treatment.

The NCI will also place new emphasis on the development process—the translation of basic research advances into new products that are ultimately delivered to cancer patients. This is especially true in the area of cancer therapeutics. It currently takes 15–20 years for a promising new molecule to reach patients. That is just unacceptable in the 21st century. Genomics and proteomics are providing us with hundreds, potentially thousands, of new therapeutic targets for cancer; but the enterprise is not optimized to develop and deliver these "new paradigm" drugs. This is a systems problem and it can be solved. In collaboration with he NIH, the Food and Drug Administration (FDA) and other partners, we will work to "re-engineer" the clinical trials infrastructure for the evaluation of new cancer interventions. Underpinning all of these initiatives will be the deployment of a bioinformatics infrastructure that will allow us to use artificial intelligence to convert massive amounts of data into new knowledge that will inform discovery, development, and delivery to benefit patients.

The NCI will undertake programs to optimize the process of developing new drugs trough an emphasis on validating new cancer targets. We will also work more closely with the FDA to facilitate the science necessary to create a seamless system of drug discovery, development, and delivery. To achieve these goals, the NCI will create novel partnerships with all of the sectors involved in developing and delivering these new drugs. In all that we do, we will encourage the removal of barriers that separate us by creating a new environment that encourages and rewards multi-disciplinary research.

The emerging field of proteomics provides us with unimagined opportunities to apply these new targeted therapies and preventive strategies by detecting cancer early enough to stop, slow, or possibly reverse disease progression. Novel disease biomarkers are finally providing us with new screening tools to detect early-stage cancer in populations and individuals; and the NCI will utilize its enormous strength in molecular epidemiology to provide rational strategies for cancer prevention and disruption of progression within populations.

All of these tactics will be directed to reducing suffering and death from cancer. That does not mean that we will lessen our emphasis on curing cancer—quite the opposite—but that will no longer be our only defining goal. We will also embrace the vision of changing the course of cancer by reducing its morbidity and mortality through the application of technologies and knowledge that were only a dream just a few short years ago. Those dreams can become reality.

Finally, I believe we stand at a pivotal crossroads—a defining moment in the history of this nation's effort to prevent and cure cancer. We now embark on a new course that will enable patients to live with cancer as a chronic, non-debilitating disease that doesn't threaten their vitality, careers, and families. An ever increasing body of scientific knowledge and an array of advanced technologies provide us with the opportunity to detect cancer early and preempt the progression of the disease. We will be able to remove the fear of cancer for many more people, but more importantly for those who must live with their disease, life will take on new meaning. We have within our grasp the power to eliminate the suffering and death from cancer—and we will succeed.

BUDGET STATEMENT

The fiscal year 2004 budget includes $4,770 million, an increase of $183 million over the fiscal year 2003 enacted level of $4,587 million comparable for transfers proposed in the President's request.

PREPARED STATEMENT OF DR. ANTHONY S. FAUCI

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Allergy and Infectious Diseases

(NIAID) of the National Institutes of Health (NIH). The fiscal year 2004 budget includes $4,335,255,000, an increase of $631,126,000 over the fiscal year 2003 enacted level of $3,704,129,000 comparable for transfers proposed in the President's request. The NIAID budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIAID's third annual performance report, which compares our fiscal year 2002 results to the goals in our fiscal year 2002 performance plan.

NIAID: AN OVERVIEW

Since 1948, NIAID has conducted and supported basic research into the etiology and pathogenesis of allergic, immunologic, and infectious diseases, as well as targeted research to develop new and improved interventions to prevent, diagnose, and treat these illnesses. Over the past half century, and in the past decade in particular, progress in the core disciplines of the Institute—immunology, microbiology, and infectious diseases—has been extraordinary. The rapid growth in scientific knowledge and the availability of new research tools has facilitated the development of numerous vaccines, therapies and other interventions that have saved or improved the lives of millions of individuals. For example, NIAID-supported scientists helped develop many of our most useful vaccines, including new or improved vaccines that protect against invasive Haemophilus influenzae type b (Hib) disease, pneumonia and meningitis caused by pneumococcal bacteria, pertussis, influenza, measles, mumps, rubella, chickenpox, and hepatitis A and B. These and other vaccines helped reduce infectious disease mortality in the Unites States more than 14-fold in the 20th century.

The scientific advances realized during 55 years of NAID research have been applied to long-standing global health problems such as asthma, autoimmune diseases, diarrheal diseases, malaria, and tuberculosis, as well as to diseases and pathogens that have recently emerged or re-emerged. Examples of the latter include the acquired immunodeficiency syndrome (AIDS), highly virulent influenza viruses, West Nile virus, drug-resistant microbes, severe acute respiratory syndrome (SARS), and a new kind of emerging disease—one spread deliberately by bioterrorists. As has been the case with AIDS and other emerging health crises, the NIAID response to the threat of bioterrorism has been swift and comprehensive, resulting already in important progress both in basic science and in the development of biodefense countermeasures.

NIAID BIODEFENSE RESEARCH

The anthrax attacks in the fall of 2001, which occurred soon after the horror of the September 11 terrorist assaults on the World Trade Center and the Pentagon, starkly exposed the vulnerability of the United States and the rest of the world to bioterrorism. Since the fall of 2001, NIAID has rapidly accelerated basic and clinical research devoted to the prevention, diagnosis, and treatment of diseases caused by potential agents of bioterrorism. Indeed, biodefense research spending now accounts for approximately one-third of the NIAID research portfolio. Our efforts have focused both on "Category A" agents considered to be the worst bioterror threats (smallpox, anthrax, botulinum toxin, plague, tularemia, and hemorrhagic fever viruses such as Ebola), as well as on a longer list of Category B and C priority pathogens agents that also pose significant threats to human health. The NIAID biodefense program is guided by the NIAID Strategic Plan for Biodefense Research, as well as by detailed research agendas for Category A agents and Category B and C priority pathogens. Each of these documents was prepared in consultation with blue-ribbon panels of experts, and delineates immediate, intermediate, and long-range NIAID plans for biodefense research and countermeasures development. Using the roadmap outlined in these agendas, NIAID has developed a total of 46 biodefense initiatives to stimulate research in fiscal years 2002 and 2003: 30 are new initiatives and 16 are significant expansions. During this same time period, NIAID has seen a 30 percent increase in the number of grant applications; the vast majority of these are in response to our biodefense initiatives.

The NIAID biodefense research program is anchored in the traditional NIH processes of basic biomedical research; concurrently, we are aggressively pursuing the goal of translating the findings of basic research into definable and quantifiable endpoints such as diagnostics, therapeutics, and vaccines. NIAID historically has sought to translate basic research findings into "real-world" interventions, as with the vaccines noted above. Until now, however, the path to product development has not been central to our research strategy. The attacks of September 11, 2001, and the subsequent anthrax incidents have compelled us to modify somewhat the way we do business, with an increased focus on translational research and product devel-

opment. This applied research is based on the strongest possible foundation of fundamental knowledge of pathogenic microbes and the host immune response.

As we pursue innovative biodefense countermeasures, we have strengthened our interactions with the private sector, including biotechnology companies and pharmaceutical manufacturers. Many biodefense products do not provide sufficient incentives for industry to develop them on their own, because a profitable market for these products cannot be guaranteed. Therefore, NIAID has developed public-private partnerships with industry to overcome such obstacles so that new and improved interventions against bioterror threats can quickly be developed.

A number of significant advances in understanding, treating, and preventing potential agents of bioterror already have been realized. For example, NIAID-supported scientists have identified antivirals that may play a role in treating smallpox or the complications of smallpox vaccination, as well as new antibiotics and antitoxins against other major bioterror threats. Investigators have demonstrated that existing stores of smallpox vaccine can be diluted five-fold and still retain their potency, greatly increasing the Nation's available stock of smallpox vaccine. These studies of diluted smallpox vaccine helped fulfill an immediate goal delineated in our strategic plan for biodefense. In the intermediate-term, new and improved vaccines against smallpox, anthrax, and other potential bioterror agents are being developed and evaluated at NIAID intramural facilities, as well as by our grantees and contractors in academia and industry. One of these is a smallpox vaccine based on a strain of the vaccinia virus that replicates less robustly than the traditional smallpox vaccine virus, and is known to be less reactogenic than the current smallpox vaccine. In the long-term, we will develop even safer vaccines against smallpox virus and other pathogens.

Advances in biodefense, as well in other areas of infectious diseases research, are being facilitated by the detailed information about pathogens that now can be rapidly gleaned by determining their genomic sequence. The field of pathogen genomics has made remarkable progress: sequencing of the genomes of more than 100 pathogens is complete or nearing completion. Among them are approximately 30 different Category A, B and C agents, including multiple strains of the anthrax bacterium. This genomic information is being used to inform the development of new antimicrobials, vaccines, and diagnostics.

Progress in biodefense research depends on the availability of research resources, such as animal models, standardized reagents, and appropriate laboratory facilities, as well as on human capital, that is, well-trained investigators. Among many initiatives to improve the biodefense research infrastructure, NIAID will establish in fiscal year 2003 a nationwide network of Regional Centers of Excellence for Biodefense and Emerging Infectious Disease Research, and design, build, and renovate a system of Regional and National Biocontainment Laboratories. These facilities will include a small number of Biosafety Level-4 (BSL-4) laboratories, which have the containment safeguards necessary to study highly pathogenic organisms. The new Centers and laboratories will serve as national resources for biodefense research and product development, as well as for the study of other emerging diseases such as influenza and West Nile virus.

The many new NIAID initiatives in biodefense research will provide benefits far beyond protection from deliberate acts of bioterrorism. After all, the general philosophy and strategy of biodefense is essentially the same as that for defense against naturally emerging and re-emerging infectious diseases that threaten global public health. With the careful NIAID planning process, new biodefense resources will unquestionably have enormous benefits in our struggle against other diseases, endemic and emerging, that far transcend the specter of bioterrorism.

ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

Another major focus of the Institute, accounting for approximately one-third of NIAID spending, is research devoted to finding interventions to slow the pandemic of the human immunodeficiency virus (HIV), the cause of AIDS. HIV/AIDS is the defining health crisis of our generation, having claimed well over 20 million lives since the beginning of the pandemic. Another 42 million people worldwide are living with the virus. Most of the world's HIV-infected people live in resource-poor countries, where HIV frequently is superimposed on other significant health challenges, including endemic diseases such as malaria and tuberculosis, and malnutrition. By 2010, more than 45 million new infections will occur, for a cumulative total of 105 million infections, according to estimates of the Joint United Nations Programme on HIV/AIDS.

Despite these grim numbers, significant progress has been made against the HIV/AIDS, much of it due to the research and prevention efforts of NIAID and other

NIH Institutes, the Centers for Diseases Control and Prevention, and other agencies of the Department of Health and Human Services. In this country, prevention efforts have reduced the annual number of new HIV infections in the United States from approximately 150,000 per year to about 40,000 annually. In recent years, we have seen the positive impact of advances in HIV therapeutics for many living with HIV/AIDS in the United States and other western countries, and more recently the promise these medicines offer for those in the developing world. All but one of the 19 antiretroviral drugs licensed in the United States target one of two viral targets: the HIV protease enzyme or the HIV reverse transcriptase enzyme. Over the past few years, NIAID-supported scientists and their collaborators have identified new targets for HIV therapy and novel drugs that block other stages of the virus replication cycle. Among them are agents that block viral genes from entering the host cell nucleus, and drugs that keep the virus from attaching to or entering the cell in the first place. In the latter category, a drug known as Fuzeon or T–20 that blocks the fusion of HIV to the host cell membrane was recently approved and holds great promise for the many HIV-infected patients who harbor HIV that is resistant to current therapies.

To help turn the tide of the global HIV/AIDS pandemic, NIAID has established research collaborations with international colleagues to develop comprehensive approaches to the HIV pandemic in poor countries, encompassing prevention activities, antiretroviral therapy when feasible, and care of the HIV-infected person. These collaborations have yielded extraordinary results, notably in developing methods to reduce mother-to-child transmission of HIV. However, a rate-limiting factor in HIV/AIDS research efforts in developing countries has been a lack of funds for the purchase of antiretroviral drugs and for improving existing healthcare infrastructure. In January 2003, the Institute's international AIDS program received a substantial boost with the announcement of the President's Emergency Plan for AIDS Relief. This plan commits $15 billion over 5 years ($10 billion of which is new money), starting with $2 billion in fiscal year 2004, for HIV/AIDS prevention, treatment, and care in 14 of the hardest-hit countries in sub-Saharan Africa and the Caribbean. This lifesaving effort will not only reduce the suffering caused by HIV/AIDS in countries that account for 50 percent of the world's HIV infections, but will provide a framework that will facilitate NIAID research efforts to develop new and improved tools of treatment and prevention.

Many approaches to HIV prevention are being developed or refined, but the "holy grail" of HIV prevention remains the development of a safe and effective HIV vaccine. Numerous vaccine candidates have shown promise in monkey models of HIV infection, and the most promising ones are rapidly being moved into human trials on the NIH campus and in the domestic and international sites of the NIAID HIV Vaccine Trials Network.

OTHER VACCINES

In addition to developing HIV and biodefense vaccines, NIAID continues to make significant progress in the quest for new and improved vaccines for other diseases of global health importance. The NIH has three broad goals in vaccine research: identifying new vaccine candidates to prevent diseases for which no vaccines currently exist; improving the safety and efficacy of existing vaccines; and designing novel vaccine approaches, such as new vectors and adjuvants, substances that improve vaccine performance.

More than 100 vaccines currently are being developed by NIAID-funded researchers, including promising candidates against emerging diseases such as Ebola virus, West Nile virus, dengue, and dangerous strains of influenza virus. Of particular note are novel tuberculosis vaccines, which soon will enter clinical trials. These trials will mark the first time in more than 60 years that new approaches to TB vaccination have been assessed in humans. These vaccines are a tangible "payoff" of research funded by NIAID and others that led to the availability of the complete genomic sequence of the tuberculosis bacterium. The quest for a malaria vaccine received a significant boost in 2002 when researchers funded by NIAID and others published the genomic sequences of the malaria parasite Plasmodium falciparum, and one of its main mosquito vectors, Anopheles gambiae. Together, these projects are probably the most significant pathogen genome sequencing effort to date. With the availability of the human genome sequence, scientists now have detailed genomic information for each of the organisms involved in human malaria: the human host, the mosquito vector and the malaria parasite itself. This groundbreaking malaria research promises to provide new targets for vaccine development and other interventions against a disease that claims the lives of more than a million people each year, most of them children in sub-Saharan Africa.

IMMUNE-MEDIATED DISEASES

Immune-mediated diseases such as autoimmune diseases, allergic diseases, and asthma are important health challenges here and abroad. Autoimmune diseases, for instance, afflict 5 to 8 percent of the U.S. population; asthma and allergic diseases combined represent the sixth leading cause of chronic illness and disability in the United States. The past two decades of fundamental research in immunology have resulted in a wealth of new information and extraordinary growth in our conceptual understanding of the immune system and the pathogenesis of immune-mediated diseases. Researchers now know a great deal about the effector molecules that contribute to many immunological conditions, knowledge that has led to the design and discovery of drugs to block those molecules. For instance, we now have powerful treatments that selectively target several of the immune system molecules that cause inflammation, a hallmark of many autoimmune diseases. Blockers of an immune system molecule called tumor necrosis factor-alpha are now routinely used in patients with rheumatoid arthritis and other immunologic conditions.

A relatively new avenue of research suggests that it may be possible to interrupt deleterious immune responses, without dampening protective ones, and provide patients with long-term clinical benefit. The ability to induce "immune tolerance" by selectively blocking deleterious immune response holds great promise for treatment of many immune- mediated conditions, including type 1 diabetes, rheumatoid arthritis and multiple sclerosis, as well as asthma and allergic diseases. For example, researchers have shown in a small trial conducted by the NIAID-sponsored Immune Tolerance Network (ITN) that antibodies to the CD3 molecule on T-cells, given for two weeks soon after patients were diagnosed with type 1 diabetes, appeared to halt the destruction of the patients' insulin- producing cells for at least a year, preserving their ability to produce some of their own insulin. Further follow-up is underway to determine the long-term benefits of this experimental therapy; a larger trial is currently recruiting patients.

Induction of immune tolerance is also one our highest priorities in organ transplantation research. The ability to selectively block the immune response to a transplanted organ would diminish or eradicate the risk of rejection, as well as the risks and morbidities associated with current methods of immunosuppression. A trial currently underway in the ITN is using a unique approach involving simultaneous bone marrow and kidney transplantation in patients with multiple myeloma. Although only a very small number of patients have undergone the procedure, early results are encouraging, as they have tolerated their transplanted kidneys without immunosuppressive medications for up to 3 years.

Another important NIAID research focus is the development of new interventions to reduce the burden of asthma. NIAID has long been at the forefront of discoveries leading to the characterization of asthma and allergic diseases and is now vigorously pursing the translation of basic knowledge into more effective treatment and prevention strategies. The NIAID-sponsored Inner-City Asthma Study, completed in 2002, evaluated the effects of a home-based environmental intervention on asthma symptoms and health care utilization in inner-city children with moderate to severe asthma. The intervention led to an additional three weeks of symptom-free days and a 14 percent reduction in unscheduled emergency room or clinic visits in the first year of the intervention; these effects largely persisted for a year following the intervention phase. The improvement in symptoms was correlated with a reduction in levels of key allergens in the home. Building on these results, the NIAID in 2002 launched the Inner-City Asthma Consortium, to conduct clinical trials of novel immune-based agents to treat or prevent asthma.

CONCLUSION

The role of NIAID in fighting infectious and immunologic diseases has never been more important, particularly in the post 9–11 world. Working with our many collaborators in the public and private sectors, we hope to further reduce the burden of diseases endemic in the United States and abroad, to enhance our preparedness against bioterrorism, and to continue to prepare for new threats to public health that will inevitably emerge in the future.

PREPARED STATEMENT OF DR. PATRICIA A. GRADY

Mr. Chairman and Members of the Committee: The fiscal year 2004 budget includes $134,579 million, an increase of $4,060 million over the fiscal year 2003 enacted level of $130,584 million comparable for transfers proposed in the President's request.

Nursing research and nursing practice are converging to address the challenges of maintaining and improving health and healthcare in our country. During this time of heightened uncertainty in many aspects of our lives, nursing research, which informs the practice of the nation's largest number of healthcare professionals—2.7 million nurses—is critical to developing and testing interventions that improve health. Increasingly there is a need for health promotion research, which is a special strength of nursing research. This need is reflected in a recent Department of Health and Human Services (DHHS) Fact Sheet that attributes 40 percent of premature deaths to unhealthy behaviors, such as smoking and poor eating habits. Conversely, of the 30-year average gain in life expectancy in the last century, the DHHS report states that 25 of those years came from advances in public health, principally from health promotion. Consistent with the NIH Research Roadmap for the future, nursing research also focuses on multidisciplinary and clinical research. The goal is to help healthcare professionals work smarter by capitalizing on new technologies and research-tested methodologies that extend the reach and quality of their practice in promoting health, managing illness, and improving care. Now let me discuss some findings.

REDUCING POSTMENOPAUSAL WOMEN'S RISKS FOR CARDIOVASCULAR DISEASE

Heart disease is the leading cause of death in women in the United States. Even though the death rate has decreased in recent years, the benefit is less for women than men. More needs to be known about the effects of preventive strategies, such as exercise and diet, in reducing risks of the disease. We know lowering total and low density lipoprotein cholesterol (LDL-C) and raising high-density lipoprotein cholesterol (HDL-C) reduces risk of cardiovascular disease in women. Nurse researchers did a study that asked the question of why HDL-C, the "good cholesterol," drops when post-menopausal, obese women adhere to a low-fat diet. On a low-fat diet, weight loss occurs and the deleterious LDL-C decreases, but the weight loss is accompanied by a reduction of the good HDL-C. Findings of the study indicate that the causal factor for the HDL-C reduction was not the type or amount of fat the women consumed, but rather that they substituted simple sugars, such as syrups and refined sugar, for fat in their diets. What the women should have done was substitute complex sugars, such as high fiber vegetables and starches. The current American Heart Association guidelines recommend consuming 55 percent of energy from carbohydrates, without specifying complex or simple. This study points out the need to write more specific dietary guidelines that differentiate between types of carbohydrates, in addition to types of fat. This study is especially timely in an age where low-fat and fat-free foods often depend on simple sugars to improve taste.

REDUCING RISK FACTORS FOR OBESITY AND HYPERTENSION IN ADOLESCENTS

Obesity continues to be a major health problem in the United States. The Centers for Disease Control and Prevention states that about 15 percent of children and adolescents are overweight, a 4 percent increase since the last survey in 1994. The U.S. prevalence of obesity increased by 61 percent in the 9 years prior to 2001. Habits formed in childhood become the lifestyles that drive this upswing. Researchers testing an intervention in children and adolescents have been able to decrease risk factors for hypertension and obesity. As part of the Cardiovascular Health in Children and Youth study, researchers tested rural, mostly African-American middle school students in an eight-week physical activities program combining exercise and health education. Subjects were divided into four groups—exercise, education, or both, and controls. Those in the two exercise groups had a lower increase in body fat, and the blood pressure of the three intervention groups decreased compared to controls. These results demonstrate the effectiveness of regular aerobic exercise and health education programs for school-aged children to help reduce their risks for cardiovascular disease later in life.

COPING WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

People with Chronic Obstructive Pulmonary Disease (COPD), which causes discomfort at best and severe, life-altering changes at worst, report that there is little available to help improve their breathing. Shortness of breath often results in inability to work, limited social activities, and even difficulty in dressing themselves. As the nation's fourth leading cause of death, COPD affects over 22 million people. In confronting this issue, nurse investigators tested a "self management" inspiratory muscle training technique to assist patients in improving their own breathing and respiratory muscle strength. For 30 minutes, 5 days a week, over a 16-week period, patients used a mouthpiece attached to a tube with openings that gradually decreased in size to make inhalation more challenging. Following training, these sub-

jects' breathing, respiratory muscle strength, and endurance were considerably improved compared to a control group, and they could once again perform daily activities. The study also showed that subjects were able to self-manage by performing inspiratory muscle training at home without direct professional assistance.

IMPROVING CARE AT THE END-OF-LIFE CARE

Another important healthcare issue involves end-of-life and palliative care. As the lead Institute at NIH for coordinating this research, NINR supports research to improve the way the healthcare system addresses end-of-life issues. A recent study commissioned by Last Acts contributed more evidence of the need for change, concluding that the United States does only a mediocre job of caring for seriously ill and dying patients. The study also indicated that although many would prefer to die at home or in a hospice, most die in the hospital, where high tech efforts to prolong life and where patients' diminished control over decisions are common.

Nurse researchers studied the outcomes for patients enrolled in the Program for All-inclusive Care for the Elderly (PACE), a managed care program for people 55 and older. Results showed that unlike the general population, where 44 percent die in the hospital and 20 percent die at home, the numbers are almost reversed in PACE, with 45 percent dying at home and 21 percent in the hospital. Another outcome was improved consistency and predictability of care. End-of-life care is often fragmented, and in the case of advance directives, written instructions may not be honored in the hospital, since staff may not have immediate access to patient records from other care facilities. The PACE program, however, offers consistent care, thus increasing the likelihood that advance directives will be followed. PACE also helps older people develop advance directives.

NEW AND EXPANDED INITIATIVES

For fiscal year 2004, NINR plans include launching a new pediatric end-of-life initiative, stimulated by the Institute of Medicine's report: *When Children Die: Improving Palliative and End-of-Life Care for Children and Their Families.* This report concluded that pediatric end-of-life issues have received insufficient research attention. We will also support the development of ethnically and culturally sensitive interventions for those near the end of life and approaches to improve communications between care providers, patients and families.

Research on strategies for self-management of chronic illness will be expanded to include reducing symptoms related to high blood pressure, diabetes, dementia and developmental disabilities. These strategies will incorporate age, gender, and ethnic and cultural factors.

Minority men will be targeted for interventions that promote healthy lifestyles, since they have a shorter life span and a higher mortality rate than Caucasian men and all subgroups of women. NINR will stimulate research on factors that influence decision-making for healthy choices, such as nonsmoking, exercise, and proper nutrition. Other issues to be addressed include: How can these men improve management of stress? How do their families and their communities influence their health-related behaviors? Because young minority men are often underserved, studies in this area could create an important strategy for effective public health interventions to follow.

We continue to have a strong interest in the significant health disparities for minority women. NINR will expand research that targets prevention of low birthweight babies, since according to Healthy People 2010, of the Department of Health and Human Services, the incidence rate for low birthweight African-American women is twice that of Caucasian women. Puerto Rican women are also especially likely to have low birthweight infants. Issues include improving early identification and management of complications during pregnancy, such as infection, hypertension, and diabetes.

TRAINING NURSE RESEARCHERS FOR THE FUTURE

NINR is addressing the future of nursing science—how to ensure that sufficient, high-quality research continues to grow and play a fundamental role in health care. In the early 90's, and again in 2000, the National Academy of Science's National Research Council stated that the number of nurse researchers must increase. Over the next four to six years, our Nation is facing a critical nursing faculty shortage. Nurse researchers form the backbone of university faculty in schools of nursing. In rising to this workforce challenge, NINR emphasizes early entry into research careers, including fast-track baccalaureate-to-doctoral programs, to increase the number of nurse investigators. Other opportunities are made available through the

NINR Centers programs and NINR/NIH research training mechanisms and career development awards.

Our centers provide an environment and infrastructure to promote early entry into and sustained participation in research programs. NINR funds nine Core Centers, each of which offers research and research training opportunities to those in their geographic areas. We also fund nine Developmental Centers that enhance emerging research programs. Our recently-launched Nursing Partnership Centers to Reduce Health Disparities funded 17 Centers which pair research-intensive nursing schools with minority-serving schools of nursing. These Partnerships are expected to expand research on health disparities and increase the number of minority nurse investigators.

NINR is focusing on ways to integrate genetic science into nursing research, education, and practice. Strategies include facilitating lifestyle changes for those at risk, genetic counseling, and selecting optimal therapeutic interventions based on genotype. The fourth NINR Summer Genetics Institute will be offered this year. This is an intensive, eight-week genetics training program held on the NIH campus. Its goal is to produce graduates who develop successful research careers and help integrate genetic information into research and educational programs across the country.

Mr. Chairman, this concludes my remarks. I would be pleased to answer any questions you and other members of the Committee may have.

PREPARED STATEMENT OF DR. JUDITH H. GREENBERG

Mr. Chairman and Members of the Committee, good morning. I am pleased to present the President's budget request for the National Institute of General Medical Sciences (NIGMS). The fiscal year 2004 budget includes $1,923 million, an increase of $76 million over the fiscal year 2003 enacted level of $1,847 million comparable for transfers proposed in the President's request.

The NIH budget request includes the performance information required by the Government Performance and Results Act of 1993. Prominent in this data is NIH's fourth annual performance report, which compared our fiscal year 2002 results to our fiscal year 2002 performance plan goals.

AN IMPRESSIVE TRACK RECORD

Since its creation more than 40 years ago, the National Institute of General Medical Sciences has built an impressive track record as a strategic investor in the future of basic biomedical research. Though not a household name, NIGMS is highly respected in the scientific community as an Institute that nurtures the nation's brightest minds in biomedicine. Through its forward-thinking funding programs, NIGMS supports thousands of scientists nationwide whose fundamental research is laying the foundation for promising new advances in disease diagnosis, treatment, and prevention.

Perhaps the most notable indicator of that track record is the number of NIGMS-supported scientists who have won Nobel Prizes-a remarkable 53 to date. In 2002, both the Nobel Prize in Physiology or Medicine and the Nobel Prize in Chemistry went to long-time NIGMS grantees, Dr. H. Robert Horvitz of the Massachusetts Institute of Technology and Dr. John B. Fenn of Virginia Commonwealth University, respectively. Dr. Horvitz's discovery of key genes controlling cell death shed new light on illnesses such as AIDS, Parkinson's disease, stroke, and cancer. And Dr. Fenn's refinement of a technique called mass spectrometry has made it possible to analyze large molecules in biological samples, an advance now widely used for blood testing.

Our Institute's leadership in supporting biomedical science was also recognized in 2002 with the prestigious Albert Lasker Award for Basic Medical Research. NIGMS grantees Dr. James E. Rothman of the Memorial Sloan-Kettering Cancer Center and Dr. Randy W. Schekman of the University of California, Berkeley, were honored for discovering the universal molecular machinery that drives "cellular trafficking." Their work helped explain vital processes such as how insulin is released in pancreatic cells, how organs develop inside embryos, and how viruses infect their hosts.

Yet another acknowledgment of NIGMS' contributions to biomedical research came late last year when the journal Science declared the discovery of how small RNA molecules control the behavior of genes to be the top scientific achievement of 2002. Funded in large part by grants from NIGMS, this "Breakthrough of the Year" research shows promise as the basis for new therapies to treat cancer, AIDS, and other diseases.

As we look ahead to fiscal year 2004 and beyond, NIGMS is poised to help make possible even more ground-breaking advances in biomedical science. I would like to share with you some of our strategies for accomplishing this important mission.

UNRAVELING THE 3-D STRUCTURES OF PROTEINS

Fifty years ago, Drs. James Watson and Francis Crick made their famous discovery of the double-helix structure of DNA. This year, scientists will reach another milestone: the completion of a highly accurate sequence representing the entire set of genetic instructions encoded in human DNA. As the Human Genome Project achieves this landmark goal, its promise to usher in a new era of molecular-based medicine will depend on another, equally important undertaking: discovering all the proteins our genes make and the functions these cellular "workhorses" play in health and disease.

Key to this ambitious effort is the unraveling of the complex, three-dimensional structures of proteins. Determining these structures can in turn reveal how proteins function and help scientists tailor the design of new drugs to treat diseases. NIGMS is the world's single largest supporter of research in structural genomics, a field dedicated to discovering the structures of proteins using sophisticated computer-based methods.

In fiscal year 2000, NIGMS launched the Protein Structure Initiative (PSI), with the goal of determining 10,000 protein structures in 10 years. The nine pilot research centers we currently support have made significant progress in developing tools for the high-throughput determination of protein structures and have begun to yield some promising results, with potential applications in biomedicine and beyond.

In November 2002, for example, NIGMS-funded researchers at Argonne National Laboratory determined the structure of a protein knot-one of only a few such structures seen in nature, and the first found in a protein from the most ancient type of single-celled organism, an archaebacterium. The microbe that the newly discovered protein comes from is of interest to industry for its ability to break down waste products and produce methane gas.

NIGMS is considering additional activities to help the centers reach their full capability, including a materials storage bank and a database for protein production and crystallization experiments. The production phase of the PSI, during which researchers will be rapidly deriving protein structures, will begin in fiscal year 2005.

HARNESSING MATH & COMPUTERS TO SOLVE BIOLOGICAL PROBLEMS

In addition to leading the way in structural genomics, NIGMS is also at another forefront: a shift in biomedical science often called the "mathematization" of biology. This shift represents a broadening of biologists' research focus from studying how individual biological molecules behave to investigating how a large number of molecules interact with one another. In order to model and predict these complex interactions, biomedical scientists are increasingly partnering with quantitative scientists, including mathematicians, physicists, computer scientists, and engineers. Together, they are applying their combined expertise to solve particularly challenging problems in biomedicine, such as understanding embryonic development, metabolism, cell growth, and cell death.

To encourage more quantitative approaches in biological studies, NIGMS established Centers of Excellence in Complex Biomedical Systems Research. The first awards were for two center grants and seven planning grants to lay the groundwork for future centers, designed to foster a multidisciplinary research environment for develop ing innovative methods to solve biomedical problems. These centers will also lead the way in training the next generation of computational biologists.

A good example of this teamwork is the recent work by NIGMS-funded researchers who have produced the first comprehensive "script of life," describing the regulation of all the genes in yeast. Reporting in the journal Science in October 2002, Dr. Richard Young, a biologist at the Whitehead Institute for Biomedical Research, and Dr. David Gifford, a computer scientist at the Massachusetts Institute of Technology, detailed how they used advanced, high-throughput biological and computing technologies to do in weeks what would have taken years to achieve using traditional techniques.

The mathematization of biology and its importance in modeling complex biological systems were also major themes at our Institute's "Visions of the Future" meeting, held in September 2002. NIGMS invited visionary scientific leaders to identify the most important and emerging areas of biomedical research. A recurring topic of discussion was the need to develop mechanisms that encourage cooperative interactions among mathematicians, physicists, computer scientists, engineers, and biolo-

gists. Moreover, meeting participants stressed the need for more rigorous quantitative training of undergraduate and graduate students who are pursuing research careers in the life sciences.

Such interaction and training were cited as keys to realizing some of science's grandest visions. These include the development of "virtual" models—of cells, tissues, disease states, and ultimately entire organisms—as well as new imaging tools and methods for making "molecular movies" of cellular machinery. Such technologies will help fill enormous gaps in our understanding of how molecules move in three dimensions and how they interact inside living cells in real time. Through its support of research and training in computational biology and other areas that cross traditional academic boundaries, NIGMS is uniquely positioned to help turn these visions into reality.

GUARDING AGAINST INFECTIOUS DISEASES & BIOTERRORISM

As concern grows over bioterrorism and the emergence of new infectious diseases, NIGMS is designing an initiative to address this threat using computational approaches and mathematical modeling. Such models will help predict the spread of microbes, the rate of disease progression in individuals, the effectiveness of different treatment or prevention strategies, and the community response to new infectious diseases. These predictions will, in turn, provide policymakers with critical information that will help them respond quickly to the threat of a new disease or bioterrorism attack.

This new initiative follows on the footsteps of another successful NIGMS program—one dealing with the evolution of infectious diseases. Deadly viruses and bacteria can adapt to seemingly limitless environmental conditions by making rapid genetic changes, far outpacing our own ability to adapt. This microbial evolution renders previously effective drugs useless and creates a moving target for drug designers. However, by analyzing the evolution of infectious organisms, researchers now have a leg up on how to outwit potentially dangerous microbes.

One application of this area of study is antibiotic resistance, an increasing problem throughout the world. Recently, NIGMS-funded researcher Dr. Barry G. Hall of the University of Rochester developed a computer simulation of microbial evolution. Dr. Hall determined through experiment which bacterial genes are most susceptible to changes that cause resistance to commonly used antibiotics. Using this approach, pharmaceutical companies could create drugs for which bacteria have no evolutionary escape route.

NIGMS is also leading the way in supporting structural studies of infectious diseases. For example, the final piece of the anthrax puzzle—the structure of the third toxic protein responsible for the deadly effects of the anthrax bacterium—was discovered last year by Dr. Wei-Jen Tang of the University of Chicago. The toxin, edema factor, causes potentially lethal swelling and fluid buildup in the body. By completing the detailed, three-dimensional the structure of edema factor, Dr. Tang also found that the protein appears to be an ideal drug target, opening the door to a possible new compound to combat anthrax infection, as well as other bacterial diseases.

BASIC RESEARCH: A VITAL RETURN ON INVESTMENT

In closing, it is worth noting that our leading efforts in structural genomics, computational biology, complex biological systems, and multidisciplinary collaboration give NIGMS a pivotal role to play in the trans-NIH "Roadmap" initiatives. Through its partnerships with other NIH institutes and centers, NIGMS will help forge new pathways to discovery and research teams of the future.

It is also important to emphasize that all of the scientific advances I have shared with you today resulted from investing in basic research on fundamental biological processes—the central mission of NIGMS. As administrators of federal research dollars, we are asked to show what we have done to ensure the best possible return on that investment, and to show how we plan to continue doing so in the future. I hope that the examples I have mentioned—from our Nobel Prize—winning achievements to our cutting-edge initiatives-illustrate the tremendous value of basic biomedical research to the strength of our scientific workforce, the security of our nation, and the health of our people.

Thank you, Mr. Chairman. I would be pleased to answer any questions that you may have.

PREPARED STATEMENT OF DR. GLEN R. HANSON

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute on Drug Abuse. The fiscal year 2004 budget includes $995,614 million, an increase of $34,496 million over fiscal year 2003 enacted level of $961,118 million comparable for transfers proposed in the President's request.

NIDA LEADERSHIP

I have been very fortunate and privileged to serve as the Acting Director of the National Institute on Drug Abuse for the past year and a half during a time of burgeoning scientific advances that have dramatically increased our understanding of brain, behavior and addiction. I am extremely confident that the incoming Director for NIDA, Dr. Nora Volkow, will be a strong leader and advocate for drug abuse research. I am pleased to have this final opportunity to showcase some of NIDA's most exciting advances and discuss how these and other research findings are resulting in tangible benefits that will improve the Nation's health.

PUBLIC/PRIVATE VENTURE YIELDS NEW MEDICATION FOR ADDICTION

An important example of how NIDA-supported research is decreasing the tremendous economic and human costs associated with drug abuse and addiction, while meeting the national need for quality treatment, is by bringing a new medication to the clinical toolbox of health care professionals. Buprenorphine, approved by the Food and Drug Administration in October 2002, is the first medication ever available for the treatment of opiate dependence that can be prescribed and dispensed by qualified physicians in an office setting, rather than at a specialized addiction treatment clinic. The nearly 1 million people who suffer from heroin addiction will benefit from the historic collaborations that took place between legislators who passed the Drug Addiction Treatment Act of 2000, Federal agencies, and the private sector (Reckitt Benckiser Pharmaceuticals) to bring this new medication to market. Buprenorphine marks the second medication to come directly out of NIDA's relatively short investment in its Medications Development Program. Developing medications for other drugs of abuse, particularly stimulants like cocaine and methamphetamine, is a top priority for the Institute, as is our commitment to develop practical and more effective science-based behavioral therapies.

NEW TARGETS FOR MEDICATIONS DEVELOPMENT

Building on a series of discoveries regarding the effects of marijuana on the brain, researchers discovered a new neuromodulatory called the cannabinoid system, which is involved in pain regulation, memory, appetite, and addiction. This system was named after the active ingredient in marijuana, tetrahydrocannabinol. Researchers from NIDA's own intramural program have used a compound that blocks cannabinoid receptors to demonstrate that the mood altering and cardiac effects of marijuana in humans can be suppressed. Additionally, they discovered that the cannabinoid system may also be involved in relapse to other drug addictions. In animal models, this same blocking compound prevented drug-seeking for cocaine following exposure to two of the three conditions that typically trigger relapse in human addicts. The discovery of this new brain system has opened the door for the development of new treatments for addiction to a variety of drugs, including cocaine and alcohol, and may also prove useful for treating obesity and pain. As we continue to unravel the complexity of the brain and identify new systems, molecules, proteins, and genes that can be exploited for therapeutic development, the need for a repository or molecular library where this information can be stored and shared with other scientists increases. This is the goal of the proposed Molecular Libraries project in the trans-institute NIH Road Map Initiative. We hope to work with the pharmaceutical companies to more rapidly develop novel and even more effective therapeutic strategies for addiction and other brain diseases that have historically been extremely difficult to treat and control, and are often overlooked by pharmaceutical companies.

STRESS AND THE BRAIN

We also are becoming increasing knowledgeable about the impact of stress on brain function. Stress can be a major factor in both the initiation of drug abuse and is known to be one of the most powerful triggers to relapse to drug abuse in former addicts. Nowhere was this more apparent than in a study published last year following the September 11th attacks in Manhattan. Twenty-nine percent of the 1,000 respondents interviewed 1–2 months following the event reported an increase in

substance use, with the highest rates in those reporting symptoms of Post-Traumatic Stress Disorder and/or depression. A study released just last month in the journal, Neuron, elucidated one of the ways in which stress and drugs of abuse produce a similar adaptation in the brain through an effect on dopamine neurons. As we progress in our understanding of the ways in which stress and drugs of abuse affect common mechanisms, we can develop prevention and treatment strategies that more effectively satisfy the needs of patients, particularly those who suffer from comorbid substance abuse and mental disorders.

THE ROLE OF GENETICS AND THE ENVIRONMENT IN ADDICTION

Powerful new technologies, such as microarrays, 3-dimensional brain mapping, and animal knockouts are accelerating the pace of science and helping us to identify the roles that genes play in addiction. One gene in particular (FAAH) produces an enzyme involved in the breakdown of the brain's natural cannabinoid compound. A recent study showed that a genetic variation in this gene was found more frequently in people who abused drugs compared to those who did not. As other genes that increase the risk of addiction are identified through NIDA's Vulnerability to Addiction Research Initiative, it becomes even more imperative that we understand how the environment can modify this risk. Basic research is giving us important insight into this complex domain of gene-environment interactions. A recent study conducted in monkeys using brain imaging techniques found that the animal's social environment can modify its neurobiology and ultimately its likelihood to self administer drugs of abuse like cocaine. When monkeys were housed together, the ones displaying dominant behavior were shown to have altered expression of D2 receptors, which are important components in the brain's reward pathway. They also were less prone to self administer cocaine (a model of cocaine abuse). This illustrates that the natural state of the dopamine system is altered by the environment, which in turn influences the likelihood of using drugs of abuse. Future studies which determine the interplay between genetic and environmental factors will be important in gaining further insight into the prevention and treatment of drug abuse and addiction.

REDUCING TOBACCO USE BY FIGHTING THE ADDICTION

Tobacco use is responsible for more that 430,000 deaths per year among adults in the United States, making it one of the Nation's top preventable causes of death. It is addiction to nicotine that continues to drive the use of tobacco, and why NIDA's expertise concerning the neurobiology of nicotine and the mechanisms of the addiction process, is so integral to the national effort to reduce this public health burden. NIDA supported research has already paved the way for a number of treatments, including behavioral therapies, nicotine-replacement approaches such as the patch and gum, and Zyban®, that help people conquer their addiction. But we must accelerate our efforts to help the estimated 48 million people according to a 2000 Surgeon General Report who remain addicted to this drug. Capitalizing on new knowledge about the biological substrates and behavioral mechanisms of nicotine and tobacco addiction, NIDA has joined with other NIH institutes to launch a number of new activities to more rapidly translate tobacco addiction research into new treatments. NIDA is also supporting research that focuses on preventing adolescents from starting to smoke.

GOOD NEWS IN PREVENTION RESEARCH

There is good news in the epidemiology and prevention arena. NIDA's long-standing annual Monitoring the Future Survey, which measures drug use among 8th, 10th, and 12th graders, showed substantial decreases in the overall use of all illicit drugs, as well as a reduction in the use of cigarettes, marijuana, club drugs, and alcohol in the past year. One of the most encouraging findings is the significant drop in the use of MDMA (Ecstasy), the abuse of which had been rising at alarming rates in recent years. We attribute these downward trends, in part, to our prevention and education efforts. As a by product of our dissemination of science-based information about all drugs of abuse, America's youth are able to weigh the facts about drugs and are making better health decisions. Understanding adolescent decision-making is an important research area being addressed in NIDA's prevention portfolio. By elucidating the cognitive expectancies of how an adolescent makes the initial and subsequent decisions to try or not to try drugs, we will gain new insight into how to develop interventions aimed at changing the actual decision to use drugs. Preventing the initial use of drugs and stopping the progression of drug use before it escalates to addiction are two targeted objectives of NIDA's National Prevention Research Initiative. The multi-disciplinary teams of basic researchers, community leaders, prevention specialists, clinicians, and health service providers who have

been brought together as part of this Initiative will use the power of science to reduce drug use in the country.

COMBATING HIV/AIDS, HEPATITIS DOMESTICALLY AND INTERNATIONALLY

Our efforts to reduce the burden of drug abuse goes beyond our borders. Given the growing number of countries that report HIV and hepatitis C infection associated with drug injection behaviors, NIDA supports a strong research program that is yielding findings that are beneficial both domestically and internationally. In the absence of a vaccine or cure for AIDS, comprehensive HIV prevention strategies are the most cost effective and reliable approaches for preventing new HIV infections, and other bloodborne infections, such as hepatitis C. NIDA-supported researchers are making progress in curtailing the spread of these diseases. NIDA researchers, using molecular biology techniques, have recently shown that new outbreaks of HIV infection among injection drug users are spreading along drug trafficking routes and spreading from drug users to non-drug using individuals through sexual transmission. Some of the victims of such transmission are homeless U.S. adolescents and AIDS orphans. Understanding how drug use related HIV transmission occurs is critical to the development of culturally specific behavior change strategies. NIDA remains committed to work with other Institutes and federal agencies to discover more effective ways to stop drug abuse-related spread of these infectious diseases and work towards transferring these evidence-based strategies to slow the spread of HIV and other related infections.

CLINICAL TRIALS NETWORK DOES MORE THAN JUST TREAT PATIENTS

HIV prevention interventions are some of the new protocols being developed for testing in NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN). The CTN, which was established in 1999, provides a national infrastructure to bring science-based behavioral and pharmacological treatments for addiction into diverse patient and treatment settings across the country. NIDA added three new sites in the past year, which now allows our 17 centers or nodes to better serve patients across a wider geographic area, in fact through the 115 community treatment programs involved in this endeavor we are serving patients in 27 states. Over 8,000 patients are expected to be enrolled in treatment protocols that are addressing the unmet needs of diverse populations, including adolescents, pregnant women, and women who suffer from Post-Traumatic Stress Disorder. Clinical trial networks for cancer and diabetes have been active for decades, but NIDA's efforts are the first ever to establish this model for addiction. Another first for the field, is the unprecedented efforts being taken to reduce the lag time between translating research discovery into practice. NIDA is working with the Substance Abuse and Mental Health Services Administration to disseminate science-based treatments into SAMHSA-supported Centers and activities. Blending the expertise of researchers, practitioners, and service-oriented professionals is the hallmark of the CTN, and why the CTN has become more than just a way to get quality treatment. It is the conduit through which research meets practice.

CONCLUSION

Reducing the adverse health, economic, and social consequences of drug abuse to individuals, families, and communities is the ultimate goal of our Nation's investment in drug abuse research. That goal is being met by NIDA.

PREPARED STATEMENT OF DR. RICHARD J. HODES

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute on Aging (NIA) for fiscal year 2004. The fiscal year 2004 budget includes $994,411,000, an increase of $1,342,000 over the fiscal year 2003 enacted level of $993,069,000 comparable for transfers proposed in the President's Request. The NIH budget request includes performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's third annual performance report, which compared our fiscal year 2001 results to the goals in our fiscal year 2001 performance plan.

There are today approximately 35 million Americans ages 65 and over, according to the U.S. Bureau of the Census. Thanks to improvements in health care, nutrition, and the overall standard of living, these men and women are more likely than ever before to be healthy, vigorous, and productive: A recent meta-analysis of demographic studies confirms that disability among America's elders has declined stead-

ily over the past decade. More older Americans are able to participate in "instrumental activities of daily living," such as performing household chores and managing their own medications, while fewer are experiencing limitations in basic physical tasks such as walking or climbing stairs. The prevalence of severe cognitive impairment also appears to be declining, although this finding needs verification.

At the same time, diseases of aging continue to affect many older men and women, seriously compromising the quality of their lives. For example, more than half of all Americans over age 65 show evidence of osteoarthritis in at least one joint.[1] Over half of Americans over age 50 have osteoporosis or low bone mass.[2] Cardiovascular disease, cancer, and diabetes remain common among older Americans. And, according to the Alzheimer's Association, as many as 4 million Americans suffer from Alzheimer's disease (AD), the most common cause of dementia among older persons.

CONQUERING ALZHEIMER'S DISEASE

We have made progress in several important areas of AD research. For example:

We are improving our ability to diagnose AD early.—Scientists are developing and refining powerful imaging techniques that target anatomical, molecular, and functional processes in the brain. These new techniques hold promise of earlier and more accurate diagnosis of AD, as well as improved identification of people who are at risk of developing the disease. For example, researchers have developed a new method of functional magnetic resonance imaging (fMRI) based on oxygen use by the brain during rest. This technique permits visualization of signals from minute subregions of the hippocampus, a brain region important for learning and memory that shows degenerative changes in AD, and the researchers are using it to distinguish between hippocampal changes that are related to normal aging and those that may indicate the presence of neurodegenerative disease. Other researchers are working to improve our ability to image AD's characteristic amyloid plaques and neurofibrillary tangles in vivo, which will allow us to diagnose the disease with greater accuracy and more closely follow its progression. These and other NIA-funded neuroimaging studies support the broader goals of the molecular imaging component of the NIH Roadmap Initiative.

We are developing new, more effective treatments and preventive interventions for AD.—Research into the underlying biology of AD is suggesting new ways to treat the disease or even prevent it altogether. For example, human stem cells, with their unique capacity to regenerate and give rise to many tissue types, are of particular interest in AD research because of their potential ability to generate new cells that could renew damaged brain tissue, replace dying neurons, or enhance the ability of the brain to respond to age-related impairments. Recent findings suggest that both human embryonic stem cells (hES), which can give rise to many cell types, and "adult" stem cells, which develop into a specific cell type, show promise for the eventual treatment of AD and other neurodegenerative conditions. Researchers have recently developed a method for inducing hES cells to differentiate into neurons. These newly-derived cells exhibit the properties of cells ordinarily found in the brain and central nervous system, suggesting that hES cells could provide a source for neural progenitor cells and mature neurons for therapeutic use. Investigators have also found that in the adult hippocampus, neural stem cells can give rise to functional neurons that can integrate effectively into existing neural circuits.

NIA is currently supporting 18 AD clinical trials, seven of which are large-scale prevention trials. These trials are testing agents such as estrogen, anti-inflammatory drugs, and anti-oxidants for their effects on slowing progress of the disease, delaying AD's onset, or preventing the disease altogether. Other intervention trials are assessing the effects of various compounds on the behavioral symptoms (agitation, aggression, and sleep disorders) of people with AD. The design and implementation of all of these clinical trials will be carried out in the context of the NIH Roadmap initiative to enhance clinical research infrastructure and methodology.

We are working to reduce the burden on caregivers of persons with AD.—Most Americans with AD are cared for at home by an adult child or in-law, a spouse, another relative, or a friend. For this reason, the AD "patient" is, in a sense, not only the person with the disease, but the entire family unit. The NIA's REACH Project (Resources for Enhancing Alzheimer's Caregiver Health), a large, multi-site intervention study aimed at family caregivers of AD patients, was designed to charac-

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[1] See "Handout on Health: Osteoarthritis," National Institute of Arthritis and Musculoskeletal and Skin Diseases, July 2002.

[2] See *America's Bone Health: The State of Osteoporosis and Low Bone Mass in Our Nation*. National Osteoporosis Foundation, February 2002.

terize and test promising interventions for enhancing family caregiving. Nine different social and behavioral interventions were tested, and investigators found that the combined effect of interventions alleviated caregiver burden, and that interventions that enhanced caregiver behavioral skills reduced depression. The second phase of the study, REACH II, combines elements of the diverse interventions tested in REACH into a single multi-component psychosocial behavioral intervention and is ongoing.

UNDERSTANDING THE BIOLOGY OF AGING

We are continuing to advance our understanding of the molecular and cellular changes that underlie aging processes, with the goals of identifying the factors that affect the life span of an organism and using this information to develop interventions to extend life and delay the onset of disease and/or disability.

Experiments in a number of animal models are providing valuable insights into mechanisms of longevity. Investigators recently created a transgenic mouse carrying a mutation in the *Xpd* gene, which codes for an enzyme involved in both repair of DNA damage and transcription of DNA into RNA (an important first step in gene activation). These mice appear normal at birth but age rapidly and live only about half as long as normal mice. This new mouse model will be useful for studying a number of aspects of aging, including the roles of DNA damage and cell death, as well as mechanisms by which the genome maintains itself and how such maintenance contributes to longevity.

Researchers are also using animal models to identify interventions that might be useful in delaying aging. For example, in one recent study, fruit flies fed the chemical 4-phenylbutyrate throughout adulthood lived significantly longer than expected, with no negative effects on physical activity, stress resistance, or fertility. In addition, last year the NIA issued a Request for Applications (RFA) for the Aging Intervention Testing Program, a large-scale initiative to test intervention strategies that may slow the rate of aging in animal models. A number of unproven strategies are already in substantial and growing use by older Americans; positive results using such strategies in animals could lead to clinical trials to establish safety and efficacy in humans. An important secondary goal is to identify interventions that are not safe or are ineffective.

Work in animal models is also leading to the identification of genes involved in regulation of the life span. In the tiny worm *C. elegans*, researchers used a sophisticated genetic screen to identify about 200 genes that cause an increase in longevity; many of these genes were related to the worm's mitochondria (cellular energy centers), while the exact function of many others remains unknown.

Such findings in model systems, as well as our increasing understanding of genetic disorders such as Hutchinson-Gilford progeria syndrome that exhibit features of premature aging, suggest important roles for genes in human aging. Evidence for a genetic basis of human longevity was strengthened by the recent finding that siblings of centenarians have about half the risk of dying at every age compared with people who do not have a centenarian sibling. In the same study, the investigators found that brothers of centenarians were at least 17 times more likely to reach the age of 100 themselves; sisters were at least 8 times more likely to reach 100 years of age.

REDUCING DISEASE AND DISABILITY

Evidence of the beneficial effects of exercise on older people continues to increase. In a study last year, researchers assessed the results of a resistive strength training program on men and women in two age groups, 20–30 and 65–75. They found that the effects of the program did not differ between the two groups: Participants in both age groups increased strength and showed similar increases in muscle mass and in resting metabolic rates, which generally decrease with age.

NIA is working to translate research findings in action through its highly successful campaign to encourage older people to exercise. Since the campaign was launched in 1998, NIA has distributed nearly one half-million copies of its exercise guide and almost 60,000 copies of its companion video to the public. A Spanish-language version of the guide was published in January 2002, and over 50,000 copies were distributed last year.

We are also working to reduce the troubling health disparities that still exist among different racial and ethnic groups. In one study of elderly heart attack patients, researchers found that black patients did not live as long after discharge from the hospital as white patients. Much of this disparity could be explained by the lower rate of use of certain cardiac procedures among black patients, suggesting

that expanded use of effective procedures could substantially reduce racial differences in long-term survival.

To address disability and disease in special populations, NIA implemented a major new study of health disparities among different racial, ethnic, and socioeconomic groups. The study, Healthy Aging in Nationally Diverse Longitudinal Samples (HANDLS), focuses primarily on cerebrovascular health, cardiovascular health, age-associated changes in cognition, and strength and physical functioning. Through this study, we hope to address hypotheses about aging and health disparities in minority and poor populations to understand the significance of environmental and genetic risk factors for disease. The pilot phase of HANDLS, in which investigators assessed the logistics and feasibility of this community-based study, was completed at the end of 2001, and the larger population-based phase of this study is scheduled to begin in late fall of 2003.

Other areas of research interest include:

Diabetes.—Last year, investigators in the multi-institutional Diabetes Prevention Program (DPP) reported that people who are at high risk for diabetes can sharply reduce their risk through a low-fat diet, and a moderate exercise regimen. This effect was most pronounced among study participants age 60 and over. Treatment with the drug metformin (Glucophage®) also reduced diabetes risk among study participants, but for unknown reasons was less effective among older participants. With other participating NIH Institutes, we are continuing to follow up the DPP participants to determine long-term effectiveness of these interventions.

Menopause.—Women approaching menopause may experience a variety of uncomfortable symptoms, but uncertainty remains over the safety of hormonal therapy due to reports of serious health risks related to some combinations of hormones. NIA-supported researchers are working to find effective treatments for the symptoms of menopause that do not increase risk of adverse effects.

CONCLUSION

It is becoming increasingly obvious that old age need not be associated with illness, frailty, or disability. In fact, we have made tremendous progress against all of the major diseases and conditions of aging. However, much work remains to be done. NIA is committed to supporting high-quality research to address all aspects of aging, from conditions and diseases that primarily affect older people to physical, behavioral, and cellular characteristics of the aging process. As more Americans live longer, NIA will meet the challenges of our rapidly aging society by continuing and intensifying research that improves the health and well-being of older people.

PREPARED STATEMENT OF DR. THOMAS R. INSEL

Mr. Chairman, and members of the Committee, I am pleased to present the President's budget request for the National Institute of Mental Health (NIMH) for fiscal year 2004, a sum of $1,382 million, which reflects an increase of $42 million over the fiscal year 2003 enacted level of $1,340 million comparable for transfers proposed in the President's budget.

In my statement, I will call to your attention the immense burden on our Nation of mental and behavioral disorders. In addition, in the context of a brief review of our research activities and accomplishments, I will suggest how NIMH's expertise in behavioral science and behavioral neuroscience are contributing to the Nation's capacity to prepare for and respond effectively to the psychological impact of bioterrorist attack.

THE BURDEN OF MENTAL ILLNESS

Mental disorders are real illnesses that are mediated by the brain and can be diagnosed reliably and accurately. Thanks to the Nation's willingness to invest generously in research, highly effective treatments exist for most mental disorders; and recovery is a realistic and attainable goal for many people who have a mental disorder. Despite our research progress, our society faces a pressing need to strengthen the quality and accessibility of clinical services for mental disorders for all those who require such services. In keeping with our public health mission, NIMH assigns high priority to the task of moving information gained through research into the hands of providers, systems, patients, and families.

The Surgeon General's Report on Mental Health noted that an estimated 5.4 percent of Americans adults have a serious mental disorder such as schizophrenia, major depression, and bipolar in a given year, and about 5- to 9 percent of children and adolescents suffer from mental and behavioral disorders that are sufficiently se-

vere to cause academic, social, or family impairment. Research supported and conducted by NIMH has significantly strengthened the ability of the Nation's health care providers to treat and manage these disorders; still, the public health challenge posed by mental illness remains formidable, in large part because many serious mental disorders tend to strike in childhood, adolescence and young adulthood, and to persist across much of a person's lifetime.

THE PRESIDENT'S NEW FREEDOM COMMISSION ON MENTAL HEALTH

With the release of the final report of The President's New Freedom Commission on Mental Health scheduled for this Spring, efforts to translate our science into clinical service programs will assume added importance and urgency. The Commission was charged to identify specific examples of community-based care models that are demonstrably successful in achieving desired outcomes. In its interim report, the Commission noted that much can and is being done to improve the delivery of high quality mental health care. The Commission found, however, that the national mental health care system is hampered by fragmentation of services and limited access to effective treatments. We have worked closely with the Commission over the course of its study, and look forward to helping to implement the its recommendations.

An ongoing collaboration between NIH and the Substance Abuse and Mental Health Services Administration (SAMHSA) anticipates the Commission's interest in ensuring that individuals in every region of the country have access to the best available treatments. NIMH, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism have identified specific treatment and preventative interventions that have a strong scientific evidence base and we are working with SAMHSA officials as they develop plans to assist State agencies implement these interventions. Built into this initiative are processes designed to establish a systematic feedback loop that will enable researchers to draw on real world experiences with evidence-based practices in order to inform and guide future intervention research.

Need clearly exists for NIMH to advise SAMHSA of completed research that will improve the quality of care available immediately. Still, opportunities have never been greater for fundamentally revamping our approaches to developing new clinical treatments and preventive interventions. New scientific knowledge about the brain and behavior, as well as the emerging science of genomics, promise to yield new treatments for mental disorders that ultimately will alter the delivery of mental health care in far-reaching ways.

SEARCHING FOR SCHIZOPHRENIA VULNERABILITY GENES

After many years of searching, the recent discoveries of several putative vulnerability genes for schizophrenia have been among the most noteworthy achievements of the past year. Schizophrenia is a genetically complex disorder, in which multiple genes are involved, but no single one of them is sufficient or necessary to cause the disease. Rather, multiple genes, interacting with environmental influences, lead to illness. One newly discovered gene, called G72, plays a role in regulating the activity of glutamate, an important excitatory neurotransmitter in the brain. This is intriguing because decreased glutamate activity appears to play a key role in negative, or deficit, symptoms of schizophrenia such as social withdrawal, a lack of motivation and expressiveness, and an inability to experience pleasure. It is interesting that several of the recently discovered genes believed to be associated with susceptibility for schizophrenia may function by interfering with neurotransmitters in the prefrontal cortex (PFC) and related brain regions. For example, another newly identified gene encodes an enzyme that terminates the activity of dopamine in the PFC. In work led by an NIMH scientist, this research has identified two alleles, or variants, of this gene; one of these has been shown in clinical studies to be associated with deficits in information processing and memory, again symptoms central to schizophrenia. These discoveries highlight the biological basis for schizophrenia and may ultimately yield both diagnostic and therapeutic breakthroughs.

SCREENING FOR DRUG DISCOVERY TARGETS

One initial application of genetic discoveries will be to identify the various molecules they encode and then design medications that act on those molecules when they are implicated in various disorders. Molecular processes gone awry can serve as targets for medications designed to prevent, treat, or halt progression of a given condition. As part of an initiative included in the NIH Roadmap, NIMH is supporting research to generate a library of small molecules with novel actions that will interact with particular biological targets. Subsequent research will test these sub-

stances as candidates for the treatment of mental disorders as well as for their utility as diagnostic agents or research tools.

AUTISM

Autism represents an urgent and significant scientific and public health challenge that, given scientific opportunity and public concern, is the appropriate focus of multiple NIH Institutes. The reported incidence and prevalence of autism appears to be rising. Over the past two decades, estimates of prevalence have escalated from 1/10000 to as many as 1/250 (for autism spectrum) to 1/400 (classic autism). A recent investigation by CDC in Brick Township, New Jersey, found a prevalence rate for autism of 4.0 per 1,000 children and a rate of 6.7 per 1,000 children for the more broadly defined category of autistic spectrum disorders.

A biologically based developmental disorder, autism is characterized by qualitative impairments in social interaction and both verbal and nonverbal communication and behaviors, resulting in a markedly restricted repertoire of activities. High quality clinical care and management of children with autism can exert a draining financial toll on families.

Last year, NIMH accepted leadership of the internal NIH Autism Coordinating Committee (ACC), which operates in close communication with the larger Interagency Autism Coordinating Committee (IACC). Other NIH Institutes retain control over their own activities, such as the long-standing Collaborative Programs for Excellence in Autism (CPEAs), a network of sites funded by NICHD and NIDCD. In 2002, NIMH committed to be the primary funding source for the Studies to Advance Autism Research and Treatment (STAART) Centers program mandated by the Children's Health Act of 2000. The Institute awarded grants to develop STAART Centers, with co-funding provided by NINDS, NICHD, NIDCD, and NIEHS. Two Centers were awarded in fiscal year 2002, and six additional Centers are slated for funding in fiscal year 2003. This will complete establishment of the network, exceeding the mandate of at least five centers required by the Act.

Our research is yielding significant dividends. A recent study found risperidone, one of a newer class of anti-psychotic medications, to be successful and well tolerated for the treatment of serious behavioral disturbance associated with autistic disorder in children aged 5 to 17. Also near completion is a study evaluating the safety and efficacy of methylphenidate (Ritalin®) in treating overactivity, impulsivity, and distractibility in children with autism spectrum disorders.

PSYCHOLOGICAL IMPACT OF BIOTERRORISM

In light of the maxim that "the purpose of terror is to terrorize," prudence dictates that we use research not only to treat the consequences of terrorism, but also to help refine our ability to triage those individuals likely to be most susceptible to serious adverse neurobiological responses to a bioterroist attack and, to the extent possible, to "innoculate" the population against destabilizing or unwarranted anxiety or panic. Over many decades, NIMH has supported a robust behavioral science research portfolio that has informed us about many basic behavioral mechanisms, including those influencing group processes. More recently, we have supported studies that have examined the psychological impact of natural disasters such as floods and tornados, and the terrorist attacks in Oklahoma City in 1995 and on September 11, 2001. Behavioral science and clinical research not only provide a "top-down" systems-level context to help us understand what is happening at molecular and cellular levels in the brain in the face of overwhelming fear and anxiety, but also can help us to prepare for and treat the psychological and social consequences of such events.

A key finding of this research to date is that people are very resilient—the vast majority of victims of mass disaster and terrorist attack do not develop a psychiatric disorder. For those individuals who do, the most frequent adverse outcome is posttraumatic stress disorder, or PTSD. This is a form of anxiety disorder that occurs after exposure to an extreme stressor in which an individual experiences, witnesses, or is confronted with actual or threatened death or serious injury to self or others. Given its prevalence, disabling impact, chronicity, and treatment resistance, PTSD represents a major public health concern. Through the research we have conducted, however, we are gaining an increasingly clear understanding of what variety of psychological and behavioral problems to expect in the event of an attack and the types of services that will be needed. We know that we should expect to see increases in requests for therapy and medications for common and troubling symptoms of fear, anxiety, hyperarousal, and sleep problems. We know that survivors—particularly those with PTSD and others who may have a comorbid, or co-occurring mental disorder—actively use mental health services. In the event of a future attack, as we

move beyond needs for first aid, housing, and food, the majority of those people who were directly affected will have need for supportive counseling and assistance with resuming normal activities such as household routines, school, and work. Research that has examined the use of mental health interventions speaks to the clinical significance of subjective distress even in subjects without recognized psychiatric disorders. We also have information about who is most likely to be at risk for developing longer-term problems and, thus, as people present to health, educational and social service programs for a variety of physical and mental health problems, it will be important to apply what we know with the aim of preventing such problems. I would also note that we also are drawing on behavioral science research involving coping in response to threat to advise individuals and communities how to anticipate and lessen the emotional burden caused by trauma. It is clear that the availability of accurate information, including information about health risk, for example, blunts the anxiety- and panic-provoking nature of unjustified speculation about risk and permits people to decide on action that they can take. Research on basic behavioral processes involved in decision-making, judgment, and health risk assessment—all involved in shaping attitudes, affect, and behavior—is very useful in shaping the messages we convey to our citizens.

I will be pleased to answer any questions.

PREPARED STATEMENT OF DR. STEPHEN I. KATZ

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). The fiscal year 2004 budget includes $502.778 million, an increase of $17.005 million over the fiscal year 2003 enacted level of $485.773 million comparable for transfers proposed in the President's request.

The budget increases over the last few years have made a tremendous difference in the studies we have been able to launch, particularly in clinical research including clinical trials in a wide variety of diseases as well as the expansion of vital scientific infrastructure in a creative way. As stewards of these funds, we have worked with a wide range of advisers, both from the scientific community and from the lay public, to ensure that we target areas of greatest scientific opportunity. In addition, we worked to undertake studies that could either be done solely or better by the Federal government. I am pleased to be able to share highlights of some of the stories of progress and promise that have resulted from our investments in medical research.

PUBLIC/PRIVATE PARTNERSHIPS

One of the priority areas in the new NIH Roadmap Initiative is the development of public/private partnerships. The NIAMS has had a number of positive experiences in this area, and I will mention two ongoing examples. The first is the Osteoarthritis Initiative. Our Institute partnered with the National Institute on Aging and several other NIH components as well as with three pharmaceutical companies in launching this public/private partnership aimed at developing clinical research resources that support the discovery and evaluation of biomarkers and surrogate endpoints for osteoarthritis clinical trials. This seven-year project is being undertaken by four clinical sites and one data coordinating center, and this consortium will likely serve as a model for future endeavors that link the public and private sectors.

The second partnership involves the NIH and the Muscular Dystrophy Association (MDA). The NIH has been actively engaged in implementing the mandates of the MD-CARE Act, and has worked closely with representatives of the muscular dystrophy (MD) research and patient communities in this effort. Specifically, the NIAMS, NINDS, and NICHD have partnered to issue new research solicitations for MD cooperative research centers, and for developmental planning grants for future centers. In addition, we are developing an initiative to support the training of basic and clinical researchers to study muscular dystrophy. To underscore the importance of stimulating and supporting further work in this area, the NIH has established an MD Research Task Force, which includes NIH scientific staff, as well as researchers, clinicians, and patient representatives. This group will help ensure that we pursue all promising opportunities to boost MD research and training, and it will also complement the work of the newly established inter-agency Muscular Dystrophy Coordinating Committee, which was called for in the MD-CARE Act.

MUSCLE DISEASES

One of the most active and productive areas within the Institute's research portfolio is in the muscular dystrophies—a group of genetic diseases characterized by progressive weakness and degeneration of the skeletal or voluntary muscles which control movement. Research advances from NIAMS investments in this area include: (1) the finding that people with facioscapulohumeral muscular dystrophy (FSHD) have an exclusive association with one of the two different forms of the chromosomal region linked to the disease. This work may lead to a better understanding of the instability of the genetic locus associated with FSHD. (2) the discovery of how to reverse muscle degeneration in a mouse model of Duchenne muscular dystrophy, a genetic disorder in which muscle cells become progressively more damaged and die. Scientists have devised a way to revitalize wasting muscle by using a special viral carrier to introduce the missing dystrophin gene into the diseased muscle tissue—a finding that could eventually lead to gene therapies for patients with Duchenne muscular dystrophy. (3) the report that a faulty gene is key to understanding myotonic dystrophy. The genetic defect affects the conductance of electrical signals, resulting in delayed muscle control. (4) the isolation of muscle-generating stem cells that can improve muscle regeneration and deliver the missing protein dystrophin to damaged muscles in a mouse muscular dystrophy model. These results signal that some of the major obstacles to stem cell transplantation may be overcome, resulting in more effective treatments for muscular dystrophy and other muscle-related diseases. and (5) the creation of a new animal model that has been labeled a "marathon mouse," which expresses an energy-metabolizing protein that increases the proportion of particular muscle fibers that give distance runners their muscular stamina. Further work in this area could benefit research efforts against muscle-wasting diseases like the muscular dystrophies.

SYSTEMIC LUPUS ERYTHEMATOSUS

Some of the most promising research results in fur mission areas have come from the ability of researchers to apply the explosion of information in genetics and genomics. One example of this is the very recent research report that a particular genetic "signature" has been linked to the blood of patients with severe systemic lupus erythematosus (SLE or lupus). A team of scientists supported by the NIAMS, other parts of the NIH, and the private sector (the Minnesota Lupus Foundation and the Alliance for Lupus Research) has discovered a genetic "signature" present in some patients with lupus who develop such life-threatening complications as blood disorders, central nervous system damage, and kidney failure. These researchers analyzed thousands of genes in the blood of patients with lupus, and, surprisingly, 14 of the thousands of genes studied were linked to a subset of lupus patients with severe disease. These 14 genes are associated with a complex family of proteins involved in the regulation of immune responses, and these findings provide strong support for developing new therapies to block the affected pathways in patients with severe lupus, as well as for identifying patients most likely to benefit from these new therapies.

I want to also mention an important new clinical trial that we launched in children with lupus. The trial is designed to test the efficacy of statins (cholesterol-lowering agents) in preventing or delaying progression of cardiovascular disease in children with lupus. This research study involves 20 centers from the Pediatric Rheumatology Research Network in establishing the largest cohort of pediatric lupus patients ever prospectively studied.

BONE AND OTHER MUSCULOSKELETAL DISEASES

One dimension of the NIH Roadmap Initiative is translational research, and we know that translating the results of basic bone biology research into therapies that prevent or treat musculoskeletal diseases can have a very significant impact on public health. Development and maintenance of a healthy skeleton depends on interactions between bone and bone marrow, blood vessels, and even the central nervous system. Understanding these complex interactions will depend on studies employing genetic and genomic tools, including NIAMS-supported efforts in animal models that are expected to translate into insights guiding the development of new preventive and therapeutic approaches to conditions such as osteoporosis. In recent advances, a variety of pharmacological agents and biochemical factors, some already familiar in other contexts, has been found to have unexpected effects on bone mass. For example, the actions of the cholesterol-lowering drugs called statins, the hormone leptin (originally identified as important for controlling obesity), and nitric oxide (best known for its effects on the heart and blood vessels) all provide clues to ways

that new therapies might improve bone health. In addition, studies of the genetics of bone mass are increasingly productive, including reports of a gene that was previously unsuspected of playing any role in bone emerging as a possible key to restoring bone in cases of osteoporosis.

Research that has direct applicability to daily life of affected individuals has determined that limb reconstruction and amputation after trauma to the lower leg result in similar outcomes in terms of function. We anticipate that the findings of this study will help surgeons and patients make better informed decisions when choosing between reconstruction (limb salvage) or amputation of a limb that has been severely damaged. With a look to the future, a large United States/Canada cooperative project is now underway to resolve differences of opinion on the best way to repair the fracture of the tibia—the most common long bone fracture in the human body. Factors that will be considered in determining which of the groups being studied has a more successful outcome include how soon patients return to work and their general health status and quality of life. Finally, plans are underway for an NIH Consensus Development Conference on Primary Knee Replacement in December 2003 to address the issues that exist in this area, to review the current state of the science, and to identify directions for future research.

SKIN DISEASES

NIAMS-supported researchers recently reported exciting and promising results from their gene therapy studies in the recessive form of the devastating blistering skin disease dystrophic epidermolysis bullosa. This disease is caused by the absence of a specific gene, and researchers used a particular enzyme as the base for gene transfer. The researchers were successful in stably integrating the DNA from the missing gene into genomes of cultured skin cells from four patients with this inherited skin disease. The skin that was developed using these cells displayed stable correction of the hallmark features of this disease. These results establish a potential practical approach to nonviral genetic correction of severe human genetic disorders that require stable genomic integration of large DNA sequences.

The Institute has recently called on scientific experts and lay representatives to help us in three particular areas of skin diseases research: (1) In response to fiscal year 2002 Congressional language, the NIAMS sponsored the "Workshop on the Burden of Skin Disease" in September 2002, to discuss the elements that comprise the burden of skin diseases and their impact on public health and daily living; current knowledge and data-collection instruments, and how to access the data more effectively; and future data needs and instruments for facilitating the collection of the data. The recommendations from this workshop are being reviewed by the Institute to determine the need and path for future initiatives in this area. The lessons learned from this workshop can serve as a paradigm for other areas—all of which share the challenge of defining the burden of a disease on an individual, the family, the workplace, and society as a whole. (2) The NIAMS teamed with the National Alopecia Areata Foundation in sponsoring the Fourth International Research Workshop on Alopecia Areata in November 2002, bringing together investigators from around the country for an exchange of recent findings in alopecia areata and related fields of hair biology. Results of this workshop will guide future research in this field. (3) The Institute is planning a workshop on immune modulation in the treatment of skin diseases, which will include new treatments for psoriasis, atopic dermatitis, autoimmune bullous diseases, and other skin diseases. The workshop will focus on trying to understand how some new treatments are actually working so that we may better understand the mechanisms underlying these diseases.

HEALTH DISPARITIES

In research related to health disparities, there are four efforts that I want to highlight: (1) The NIAMS continues to support the diversity initiative it has created and developed over the last few years—the Health Partnership Program, a collaborative community-based effort in Washington, D.C., that is directed at developing research programs to understand and address health disparities in rheumatic diseases in African American and Hispanic/Latino communities. (2) Differences have been documented in the damage caused by lupus in studies of Hispanic, African American, and Caucasian individuals with this disease. The proportion of patients who had any organ damage was higher among Hispanics than among the other two groups, confirming the greater negative impact of lupus among members of this ethnic group. The association of organ damage with poor coping skills was reported for the first time, and it suggests that approaches designed to modify patients' behaviors and attitudes to their illness could reduce the damage to the body caused by lupus. (3) Research suggests that women with lupus are at increased risk for both clinical

osteoporosis and cardiovascular complications at a much younger age, and more aggressive control of the risk factors for these complications is needed to prevent these conditions in women with lupus. (4) Social experience has been shown to influence joint replacement decisions; that is, when people think about having a hip or knee replaced, knowing someone who has had the surgery may influence their decision. A recent study funded by the NIAMS and the Robert Wood Johnson Foundation suggested that one reason African Americans may be less likely than Caucasians to seek joint replacement surgery, a procedure that makes a significant difference in alleviating pain and improving function of severely affected individuals, is because they know fewer people who have had this procedure.

CONCLUSION

We are proud of the advances that scientists supported by the NIAMS have achieved and we are excited about initiatives that we have launched. Patients and their families are looking to us with hope and anticipation for answers to what causes their diseases, as well as how their diseases can be better treated and even prevented. We are confident that public health in general as well as daily life for affected individuals in particular will benefit from NIAMS research in the extensive and diverse array of chronic diseases within our mission areas of bones, joints, muscles, and skin.

I would be happy to answer any questions.

PREPARED STATEMENT OF DR. GERALD T. KEUSCH

The fiscal year 2004 budget includes $64,266,000, an increase of $2,073,000 over the fiscal year 2003 enacted level of $62,193,000 comparable for transfers proposed in the President's request.

SCIENCE FOR GLOBAL HEALTH

Thirty five years ago, the Fogarty International Center was established to honor the memory of Congressman John E. Fogarty of Rhode Island. The authorizing legislation, introduced by Representative Melvin Laird of Wisconsin, stated ". . . the committee has provided funds to plan a lasting memorial to a man who for more than a quarter of a century worked tirelessly for a healthier America in a healthier world." (Congressional Record, House, May 25, 19867, p. 14062). It is my privilege to report to you, that for the past 35 years, the Fogarty International Center (FIC) has fulfilled this promise—Mr. Fogarty and Mr. Laird would be proud of their legacy. Today the FIC is an essential component of the DHHS and NIH response to global challenges in health, representing the nexus between science and diplomacy and promoting both at the same time. FIC is known and respected around the world for its critical role in promoting research and capacity building for global health.

The research and training supported by FIC is a window to a brighter future for the low- and middle-income countries with heavy burdens of disease. While people in these countries typically suffer from high infant, child and maternal mortality rates, amplified manyfold by the threats represented by AIDS, TB, malaria and other seemingly intractable infectious diseases, increasingly these populations are now subject to the ravages of chronic disease and premature mortality represented by cardiovascular disease, diabetes, and cancer. All of these conditions limit societal productivity, economic growth, and stability. To this end FIC supports research to better understand the impact of improving health on economic development, political and social stability, and active participation in the global marketplace of the 21st century. Because economic growth invariably impacts on the environment, usually in an adverse manner, FIC has also developed a research agenda to improve our understanding of the impacts on population's health and individual's well-being related to sustainable economic development. These programs are crucial as we identify health care interventions that an improve both health and development.

The programs of the FIC directly address five of the eight goals outlined in the United Nations Millennium Declaration, including eradication of extreme poverty (Goal 1), reducing child mortality and improving maternal health (Goals 4 and 5), combating HIV/AIDS, TB and malaria (Goal 6), and ensuring environmental sustainability (Goal 7). These goals are daunting, but not incapacitating. As U.N. Secretary General Kofi Annan has said, "They are achievable, not by holding more world conferences, but by people in every country, coming together and taking action." This is precisely what FIC does every day. To maximize and leverage the impacts of FIC programs, the Center has collaborated extensively within the NIH, across the Department of Health and Human Services, and beyond, including other

components of the Federal government, bilateral and multilateral agencies here and abroad, foundations, and international organizations such as the World Health Organization, The World Bank and the Regional Development Banks.

STRENGTHENING THE GLOBAL CULTURE OF RESEARCH

For scientists to come together and take action requires them to share a common culture of scientific ethos and values. This can only be accomplished in an environment in which rapid communication is possible, wherein scientific knowledge is readily available to all, and where research is conducted based on partnership and equity. When American scientists work across geographic boundaries in this manner, the beneficiaries are the collaborating scientists, science in general, the United States and foreign partner countries.

FIC strengthens this "global culture of research" through a range of programs. The FIC International Bioethics Education and Career Development Award provides trainees with a strong background in ethics and an understanding of research. The cadre of thoughtful and knowledgeable people trained through this program will insure that internationally and United States-accepted ethical principles are upheld in studies around the world, including in poor nations. An additional component to strengthening a global culture of science is to ensure that technological advances made in one country are accessible to the greatest extent in all countries.

FIC addresses the growing divide in the development and use of genetic technologies through the International Collaborative Genetics Research Training Program. FIC-upported training in the technology of modern genetics research is accompanied by a strong component of ethical, social, and legal considerations and focuses on the mplications of performing genetics research in low- and middle-income countries.

The third pillar in support of the global culture of science is access to information, which is addressed by the International Training Program in Medical Informatics. This program enables U.S. institutions to support training in order to build the capacity of scientists in developing countries to access, utilize and construct computer-based tools to access and exchange information to advance biomedical research and public health. This program will recompete in fiscal year 2004. As a companion to this initiative, FIC in collaboration with the National Library of Medicine is embarking on additional programs to support and improve the editorial content of key biomedical research and health journals in developing countries, and to improve the quality and accuracy of reporting on medical research and health by developing country journalists, whether they are working in print, radio or television.

As FIC works to strengthen the global culture of science through all its programs, to maximize the benefits of individual initiatives in fiscal year 2004 FIC proposes to pilot innovative International Glue Grants. These grants will provide resources to link together regional and national institutions in developing countries with their several U.S. partner institutions, taking advantage of the perspective of biomedical, clinical and behavioral and social scientists in creating new ways to explore old and emerging health problems. We expect the "glue" will bring investigators together in a common framework for addressing critical issues, enabling these collaborators to work more cost-effectively and with greater productivity on critical challenges such as AIDS, maternal health, and impacts on health from environmental pollution.

Support for the movement of junior researchers across borders is the fourth pillar of the broader effort to strengthen the global culture of research and science. FIC will continue to invest in the Global Health Research Initiative Program (GRIP), which provides resources for developing country scientists who trained in the United States to obtain, on a peer-reviewed merit-based system, funding to conduct research upon their return home and remain linked in collaborative research with their U.S. mentors. As a corollary to this program, FIC is also investing in career pathways in international research for young American investigators through the FIC International Research Scientist Development Award (IRSDA). The IRSDA supports junior U.S. scientists as they conduct research in the developing world on issues of global import, then provides additional opportunities and a "safety net" on their return home. In addition, in fiscal year 2004, will bring the first crop of students of medicine, public health and allied medical sciences into a new program to provide a year of mentored clinical research training in a developing country collaborative research program. The rationale for this new program is to expose students as early as possible in their professional careers to research needs and prospects in the developing world as a means to encourage them to select global health challenges as long-term career pursuits. A partnership with the Ellison Medical Foundation, the Association of American Medical Colleges, the Association of Schools of Public Health and the FIC, the program will pair a U.S. student with

one from the host country to train and participate in clinical research under the guidance of expert mentors from the United States and the foreign country who already work together on clinical research studies.

A previously neglected area is that of gender and global health research. Not only may risk factors, disease progression, and response to treatment vary by gender, but societal responses based on gender may exclude women from accessing health care or may imbue them with stigma that adds significantly to the burden of disease. FIC is initiating two new programs to address these issues. First, the Stigma and Global Health research program, expected to be funded in fiscal year 2003, will support studies to better understand the exclusion of stigmatized populations from the benefits of medical care and participation in medical research. Importantly, it will identify interventions to address the major needs. Second, FIC, the NIH Office of Research on Women's Health, the Canadian Institutes of Health Research, and Harvard and Yale Universities are working with experts around the world to develop a framework for the inclusion of gender issues across the range of global research and training programs the Center and other science funding agencies support. Included in this initiative is an effort to enhance career development for women scientists from the developing world.

CONTINUING TO INVEST IN COMMUNICABLE DISEASE RESEARCH

FIC currently supports a broad program of research and training in AIDS, tuberculosis, malaria and other emerging infectious diseases. In fiscal year 2004 the Center will pursue these major global health problems in three ways, first through its continuing focus on AIDS, the greatest epidemic threat of our time, and second, through support of a comprehensive program, the Global Infectious Disease Training and Research Program (GLIDTR), to focus on infectious diseases that are predominately endemic in or impact primarily upon people living in tropical countries. Under the AIDS programs, a major new initiative will be fully launched with the awarding of the first set of comprehensive grants under the International Clinical, Operational and Health Services Research and Training Award for AIDS and TB (ICOHRTA-AIDS/TB). This program has as its major goal the promotion of excellent clinical research in support of care of AIDS patients, along with the necessary operational and health services research to move new knowledge into practice as soon as possible. The GLIDTR is augmented by FIC/NIH enlarging investments in the Ecology and Infectious Diseases research program, a major collaboration between FIC and the National Science Foundation. This innovative program is oriented towards identifying predictive models for emergence of infectious diseases so that preventive strategies can be implemented before a new global calamity is unleashed on the world. Finally, FIC's Division of International Epidemiology and Populations Studies is conducting and coordinating research involving mathematical modeling of epidemic disease, whether due to events in nature or caused by humans, in an effort to better identify key questions and intervention points. Working closely with NIAID, NIGMS, and the Office of Public Health Emergency Preparedness at DHHS, FIC is coordinating work with leading academic mathematical modeling groups in the United States and abroad.

EXPANDING INVESTMENTS IN NON-COMMUNICABLE DISEASES

With the aging of populations worldwide, including in poor nations, along with changing ifestyle patterns and migration into cities, there is a growing recognition that the global burden of disease will increasingly include non-communicable diseases. FIC's current programs in this broad field address the burden of mental illness, the broad range of brain disorders across the life cycle, and the major epidemic of tobacco use and the inevitable epidemic of chronic pulmonary, cardiovascular disease and cancer that will follow. To complement this set of critical issues, FIC intends to explore ways to address the huge and growing burden of morbidity and mortality due to trauma and injury, whether intentional or un-intentional, such as road-traffic accidents. Areas of interest include training and research activities designed to better understand the body's systemic responses to major injury, fostering more rapid application of this knowledge to wound healing following trauma and burns, development of innovative low-cost and low-maintenance prosthetic devices, integration of mental and physical rehabilitation into primary care for victims of trauma, and to develop and test effective cost-effective interventions.

A complete description of the FIC Strategic Plan is available on the World Wide Web at http://www.nih.fic.gov/about/plan.html.

CONCLUSION

Today, FIC, together with the Institutes and Centers at the NIH, is exerting leadership in global health research in important new ways, addressing critical global health problems while investing in the training of United States and foreign researchers who can, together, identify the solutions for tomorrow. As expressed by John E. Fogarty before his death in 1967, "The alternative is that the United States will reduce its leadership role in furthering humanitarian programs, and may become more of a responder than a leader."

PREPARED STATEMENT OF DR. RAYNARD KINGTON

Mr. Chairman, Members of the Committee: I am pleased to present the President's budget request for the Office of the Director (OD) for fiscal year 2004, a sum of $317,983,000, which reflects an increase of $44,031,000 over the comparable fiscal year 2003 appropriation. The OD provides leadership, coordination, and guidance in the formulation of policy and procedures related to biomedical research and research training programs. The OD also is responsible for a number of special programs and for management of centralized support services to the operations of the entire NIH.

The OD guides and supports research by setting priorities; allocating funding among these priorities; developing policies based on scientific opportunities and ethical and legal considerations; maintaining peer review processes; providing oversight of grant and contract award functions and of intramural research; communicating health information to the public; facilitating the transfer of technology to the private sector; and providing fundamental management and administrative services such as budget and financial accounting, and personnel, property, and procurement management, administration of equal employment practices, and plant management services, including environmental and public safety regulations of facilities. The principal OD offices providing these activities include the Office of Extramural Research (OER), the Office of Intramural Research (OIR), and the Offices of: Science Policy; Communications and Public Liaison; Legislative Policy and Analysis; Equal Opportunity; Budget; and Management. This request contains funds to support the functions of these offices.

In addition, the OD also maintains several trans-NIH offices and programs to foster and encourage research on specific, important health needs; I will now discuss the budget request for each of these trans-NIH offices in greater detail.

THE OFFICE OF AIDS RESEARCH

The Office of AIDS Research (OAR) coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. Our response to the epidemic requires a unique and complex multi-institute, multi-disciplinary, global research program. Perhaps no other disease so thoroughly transcends every area of clinical medicine and basic scientific investigation, crossing the boundaries of the NIH Institutes and Centers. This diverse research portfolio demands an unprecedented level of scientific coordination and management of research funds to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently, allowing NIH to pursue a united research front against the global AIDS epidemic.

Each year, OAR oversees the development of the comprehensive NIH AIDS-related research plan and budget, based on scientific consensus about the most compelling scientific priorities and opportunities that will lead to better therapies and prevention strategies for HIV disease. The Plan serves as the framework for developing the annual AIDS research budget for each Institute and Center; for determining the use of AIDS-designated dollars; and for tracking and monitoring those expenditures. OAR identifies scientific areas that require focused attention and facilitates multi-institute activities to address those needs. OAR coordinates, monitors and fosters plans for NIH involvement in international AIDS research and training activities. OAR supports a number of initiatives to enhance dissemination of research findings to researchers, physicians, patients and communities. The fiscal year 2004 budget request for OAR is $60,942,000.

THE OFFICE OF RESEARCH ON WOMEN'S HEALTH

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research for the Office of the Director, to ensure that women are appropriately represented in biomedical and biobehavioral research studies supported by the NIH, and to develop and support biomedical careers. The report: *An*

Agenda for Research on Women's Health for the 21st Century, provides the basis for the ORWH to collaborate with the scientific and advocacy communities to address scientific initiatives about women's health and sex and gender factors in health and disease. In fiscal year 2004, the OD budget request of $41,231,000 includes an increase of $808,000 over the fiscal year 2003 enacted budget of $40,423,000 for the ORWH to continue stimulating new research and to implement innovative career development programs.

Research priorities for women's health emphasize the importance of interdisciplinary collaboration, especially for chronic, multi-systemic conditions; prevention and elimination of high risk behaviors, such as overeating and physical inactivity, which contribute to morbidity and premature mortality of women; and reproductive health, including such gynecologic conditions as uterine fibroid tumors, and further exploring issues related to the menopausal transition, such as hormone therapy. The ORWH continues to partner with Institutes and Centers to monitor compliance with NIH policies for the inclusion of women and minorities in clinical research, and to ensure that analyses by sex/gender are addressed. The ORWH is witnessing exciting expansion of new research in its specialized centers of interdisciplinary research in women's health and sex and gender factors. The ORWH has also expanded its unique interdisciplinary career development program in women's health research that fosters the mentored development of junior faculty and assists them in bridging advanced training for junior investigators with research independence. In addition, the ORWH has now implemented a new Intramural Program on Research on Women=s Health to focus on NIH intramural women=s health and sex and gender comparison research.

THE OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH

The NIH has a long history of funding health-related behavioral and social sciences research, and the results of this work have contributed significantly to our understanding, treatment, and prevention of disease. The Office of Behavioral and Social Sciences Research (OBSSR) furthers NIH's ability to capitalize on the scientific opportunities that exist in behavioral and social sciences research by providing leadership in identifying and implementing research programs in behavioral and social sciences that are likely to improve our understanding of the processes underlying health and disease and provide directions for intervention. OBSSR works to integrate a behavioral and social science approach across the programs of the NIH. The fiscal year 2004 OD budget includes $26,179,000 for OBSSR, an increase of $513,000 over the fiscal year 2003 appropriation.

Many exciting scientific developments are occurring at the intersection of behavioral and social science research and biomedical research. OBSSR and several ICs are in the process of developing new approaches to train individuals to undertake a program of research that extends well beyond traditional disciplinary boundaries. One such initiative is a new postdoctoral program that would provide individuals trained in one discipline with formal course work and hands-on training in a second field. Collaboration between social and behavioral scientists and biomedical investigators is still relatively uncommon, in part, because traditionally trained social and behavioral researchers lack sufficient expertise in the biomedical fields and vice versa. The initiative will provide a mechanism for training investigators to work in interdisciplinary teams to tackle some of our most pressing health problems.

OBSSR is also developing an initiative that will encourage investigators to expand on the current theoretical base of change processes and intervention models, to expand our understanding of how change, once achieved, is maintained over the long term. Maintaining behavior change over the long term appears as challenging, if not more so, than the initiation of behavior change. Past research efforts have typically focused on short-term behavioral change. However, other research indicates that relapse rates for addictive behaviors such as substance abuse and tobacco use are very high. Additionally, while the positive association between education and health has been well documented, there is a paucity of scientific information on the biological mechanisms and the causal pathways that underpin this association. OBSSR in collaboration with other ICs issued a Request for Applications to increase extramural research activity on this important scientific question.

THE OFFICE OF DISEASE PREVENTION

The primary mission of the Office of Disease Prevention (ODP) is to stimulate disease prevention research across the NIH and to coordinate and collaborate on related activities with other federal agencies as well as the private sector. There are several other offices within the ODP organizational structure.

The Office of Medical Applications of Research (OMAR) has as its mission to work with NIH Institutes, Centers, and Offices to assess, translate and disseminate the results of biomedical research that can be used in the delivery of important health services to the public. The Office of Disease Prevention (ODP) has several specific programs/offices that strive to place new emphasis on the prevention and treatment of disease.

In fiscal year 2004, the Office of Dietary Supplements (ODS) within ODP requests a budget of $18,778,000. It will continue to promote the scientific study of the use of dietary supplements by supporting investigator-initiated research in conjunction with other ICs at NIH and stimulating research through conduct of conferences and through presentations at national and international meetings. In its continuing efforts to inform the public about the benefits and risks of dietary supplements, the ODS expanded the International Bibliographic Information on Dietary Supplements (IBIDS) database to include a consumer-oriented search strategy. It has also disseminated a database devoted to federal funding of dietary supplement research, called CARDS, which is currently populated with data about the NIH investment from fiscal year 1999–2001. ODS publishes Fact Sheets about vitamin and mineral dietary supplements in collaboration with the NIH Clinical Center, as well as Fact Sheets about botanical supplements in conjunction with the National Center for Complementary and Alternative Medicine. ODS, in collaboration with the National Heart Lung and Blood Institute and other NIH ICs, has sponsored a systematic review of the relationship between omega-3 fatty acids and a series of clinical indications, particularly coronary heart disease. Several reports will be published in fiscal year 2003 and fiscal year 2004 based upon this review, which will serve as the basis for planning further NIH research on omega-3 fatty acids. To determine the future research studies of efficacy and safety of dietary supplements containing ephedra, ODS sponsored a systematic review of ephedra efficacy and safety, which has recently been completed. ODS has initiated work on a pre-clinical study of ephedra by the National Toxicology Program. Congressional language in the fiscal year 2002 and fiscal year 2003 appropriation reports directed ODS to enhance an ongoing collaboration for the development, validation, and dissemination of analytical methods and reference materials for botanical dietary supplements. ODS works with other partners in the public and private sectors to meet this objective. ODS supports the National Health and Nutrition Examination Survey (NHANES), conducted by the National Center for Health Statistics at the Centers for Disease Control and Prevention, in order to provide more information about dietary supplement use in the US population. This will inform future research about potentially important target populations, such as children, women, and the elderly. Funding is used to create and populate a database of dietary supplements, as well as to support the measurement of blood levels of key metabolites associated with dietary supplement use. In fiscal year 2003, ODS and USDA published the proceedings of a workshop that examined the emerging needs for dietary assessment, including supplement use, in national surveys such as NHANES. A key outcome has been to develop an analytically-based database of dietary supplement ingredients.

Another component of ODP, the Office of Rare Diseases (ORD), develops and disseminates information to patients and their families, health care providers, patient support groups, and others and forges links among investigators with ongoing research activities in this area. The ORD supports workshops and symposia to stimulate research on rare diseases.

To provide better and faster information, ORD, together with the National Human Genome Research Institute (NHGRI), established the Genetic and Rare Diseases Information Center to respond to requests for information about genetic and rare disorders. The fiscal year 2004 budget request for ORD is $11,423,000.

The ORD, supports together with NIH Institutes and Centers research on rare diseases. Approximately 25 million people in the United States are affected by an estimated 6,000 rare diseases. A "rare disease" is defined as a condition affecting fewer than 200,000 Americans. On November 6, 2002, the President signed the Rare Diseases Act of 2002 (Public Law107–280). The purposes of this Act are to establish the Office of Rare Diseases in statute at the National Institutes of Health and to increase the national investment in the development of diagnostics and treatments for patients with rare diseases and disorders.

THE OFFICE OF SCIENCE EDUCATION

The Office of Science Education (OSE) plans, develops, and coordinates science education programs to strengthen and enhance efforts of the NIH to attract young people to biomedical and behavioral science careers and to improve science literacy in both adults and children. The office's mission is to help people understand and

use new knowledge uncovered by the NIH in pursuit of better health for everyone. The OSE works toward this mission by: creating programs to improve science education in schools (the NIH Curriculum Supplement Series); creating programs that stimulate interest in health and medical science careers (the new LifeWorks Web site); creating programs to advance public understanding of medical science, research, and careers; promoting NIH educational resources and programs; and advising NIH leadership about science education issues. All office programs target diverse populations including under-served communities, women, and minorities, with a special emphasis on the teachers of students from Kindergarten through grade 12. The OSE works closely with NIH institutes, centers, and offices on science education issues, and maintains the OSE Web site as a source of information about available resources and programs. http://science.education.nih.gov.

The NIH Curriculum Supplements series are National Science Education Standards-based lesson plans that are distributed free to K–12 teachers across the country. They incorporate the best of both science and education communities, and are intended to update science content and allow the teacher to incorporate the latest NIH research into classroom instructions. *Life Works* is a new OSE Web site created as a source of career information for students, teachers, counselors, and parents. The site will allow exploration of the educational requirements, knowledge, skills, and abilities required for over 100 health and medical science careers. The fiscal year 2004 Budget request for OSE is $3,866,000.

LOAN REPAYMENT AND SCHOLARSHIP PROGRAM

The NIH, through the Office of Loan Repayment and Scholarship (OLRS), administers the Loan Repayment and Undergraduate Scholarship Programs. The NIH Loan Repayment Programs (LRPs) seek to recruit and retain highly qualified physicians, dentists, and other health professionals with doctoral-level degrees to biomedical and behavioral research careers by countering the growing economic disincentives to embark on such careers, using as an incentive the repayment of educational loans. There are loan repayment programs designed to attract individuals to clinical research, pediatric research, health disparities research, and contraception and infertility research, and to attract individuals from disadvantaged backgrounds into clinical research. The AIDS, Clinical, and General Research Loan Repayment Programs are designed to attract investigators and physicians to the NIH's intramural research and research training programs. The NIH Undergraduate Scholarship Program (UGSP) is a scholarship program designed to support the training of undergraduate students from disadvantaged backgrounds in biomedical research careers and employment at the NIH. The fiscal year 2004 Budget request for OLRS is $6,843,000.

NIH ROADMAP

The NIH Director is taking an innovative approach to accelerate fundamental discovery and translation of that knowledge into effective prevention strategies and new treatments-an effort referred to as the NIH Roadmap. The fiscal year 2004 budget request for the Office of the Director includes an increase of $35,000,000 for strategic "roadmap" initiatives. These funds will be allocated by the NIH Director to the Institutes and Centers to address critical roadblocks and knowledge gaps that currently constrain rapid progress in biomedical research. Three broad initiatives will be stimulated with these funds: (1) new pathways to discovery, which includes a comprehensive understanding of building blocks of the body's cells and tissues and how complex biological systems operate, regenerative medicine, structural biology, molecular libraries, nanotechnology, bioinformatics and computational biology, and molecular imaging; (2) research teams of the future, including multidisciplinary research and public-private sector partnerships; and (3) re-engineering the clinical research enterprise. These efforts will allow the NIH to rethink the infrastructure that is required to translate findings from the genomic era into front-line treatments and prevention strategies that benefit people in this country and abroad..

Thank you for giving me the opportunity to present this statement; I will be pleased to answer questions.

PREPARED STATEMENT OF DR. CLAUDE LENFANT

I am pleased to appear before this Committee once again on behalf of the National Heart, Lung, and Blood Institute (NHLBI). We are extremely grateful for the generous budget increases of recent years that have enabled us to capitalize on extraordinary research opportunities.

PROGRESS AND CHALLENGES

A recent report in The New York Times ("Gains on Heart Disease Leave More Survivors, and Questions") highlighted how far we have come in the battle against heart disease—and how far we have yet to go. The well-known good news is that heart disease death rates have been plummeting for decades, and serious disease manifests itself much later in life. The bad news is that an acute problem has become a chronic problem that affects millions of Americans—this is "the endgame of the cardiovascular disease epidemic" that we now confront.

CLINICAL RESEARCH AND THE NIH ROADMAP

Our vigorous research effort is rapidly uncovering new knowledge and technologies that will undoubtedly lead to treatments undreamed of even 10 or 20 years ago. While they are being developed and tested, however, we must do our best to ensure that rigorous science guides appropriate use of more conventional treatments. Indeed, clinical research that has direct application to public health issues is a major focus of the NIH Roadmap that is currently being drawn and refined. The NIH investment in clinical research and, particularly, in clinical trials is absolutely critical if we are to provide health-care givers and their patients with science-based information to guide their decision-making. This is a role that the NIH is uniquely able to fill; indeed, it is a job that would never be undertaken without support from public funds. In this light, I am very pleased to mention some findings from recent clinical trials that have enormous practical significance for disease prevention and treatment.

BLOOD PRESSURE MEDICATIONS

The benefits of treating hypertension are widely appreciated. However, the choice of a means to achieve blood-pressure lowering has been complicated in recent years by the arrival on the market of new drugs (e.g., calcium-channel blockers, angiotensin-converting-enzyme inhibitors, alpha blockers) that, while expensive, were thought to have advantages over older drugs. The ALLHAT (Antihypertensive and Lipid-Lowering to Prevent Heart Attack Trial) compared these new drugs with a diuretic—one of a class of blood pressure-lowering drugs that has been used for many years and can be had for mere pennies a day. It found that the diuretic did at least as good a job as newer agents in preventing complications of hypertension—and a better job, according to some measures. The study was conducted in a variety of practice settings and its participants, all aged 55 and over, included high proportions of women, minorities, and persons with type 2 diabetes. Thus, the results are widely applicable to Americans with hypertension, who number about 50 million, according to the National Health and Nutrition Examination Survey.

POSTMENOPAUSAL HORMONE THERAPY

The merit of conducting rigorous research to challenge widely held, but unproven, assumptions about treatment and prevention is illustrated even more starkly by recent studies of hormone therapy in postmenopausal women. When the NIH Women's Health Initiative was started more than a decade ago, belief in the manifold benefits of estrogen—and particularly its benefits with respect to heart disease prevention—was so widespread that some thought such a trial was neither feasible nor ethical. Thus, it was major news when the trial reported last summer that a widely used form of postmenopausal hormone therapy (estrogen plus progestin) is ineffective in reducing cardiovascular disease risk and appears, in fact, to be harmful. Estimates from U.S. Census data indicate that more than 40 million American women are postmenopausal, so the implications of this trial, in terms of both health and costs, are potentially very great.

TREATING ATRIAL FIBRILLATION

Yet another example of a study that contradicted popular wisdom is the AFFIRM (Atrial Fibrillation Follow-up Investigation of Rhythm Management) trial. It compared a well-regarded rhythm-management approach to treating atrial fibrillation (an abnormal heart rhythm) with a rate-control strategy. The trial found that the purported benefits of the rhythm-management approach were nonexistent and, moreover, that the approach carried an increased risk of adverse drug effects. These findings are expected to alter fundamentally our method for preventing complications, most notably stroke, of this arrhythmia, which affects an estimated 2.3 million people in this country, according to data from the American Heart Association.

PREVENTING RECURRENT BLOOD CLOTS

Finally, the PREVENT (Prevention of Recurrent Venous Thromboembolism) trial was recently halted ahead of schedule because of persuasive intermediate results. It found that long-term use of low-dose warfarin (a blood thinner) to prevent the recurrence of two blood-clotting disorders, deep vein thrombosis and pulmonary embolism, provided major benefits without significant side effects. As was the case with the ALLHAT study, this trial addressed a research question that would never have been pursued by industry, and identified an important use for an old, very inexpensive therapeutic agent.

NEW RESEARCH TO ADDRESS CRITICAL PUBLIC HEALTH ISSUES

Two of the most pressing public health priorities of today are obesity and diabetes, conditions that have become epidemic in modern America. Both are the object of NIH-wide multifaceted efforts; they are, moreover, the special focus of concerted NHLBI attention because their victims are inordinately susceptible to cardiovascular disease complications. The NHLBI is undertaking new programs in both areas, with the ultimate goal of reducing the toll of such complications.

OBESITY

Innovative worksite interventions for preventing and controlling obesity in adults will be designed and tested. Although traditional obesity-control strategies have focused on the individual, the workplace constitutes a promising location for making positive, long-lasting behavioral and environmental changes that may affect a broad range of adults. It is envisioned that researchers will consider a variety of approaches to make healthful foods available, affordable, and desirable; promote physical activity; and establish support systems that enable achievement and long-term maintenance of appropriate weight.

A comprehensive research initiative on asthma and obesity will also be undertaken. Studies have found that body mass index is strongly and independently associated with risk of adult-onset asthma, and that excessive weight gain in elementary school greatly increases risk of developing asthma among young girls. Overweight also appears to contribute to asthma exacerbations and diminished pulmonary function. Experts from a variety of relevant disciplines believe that research conducted collaboratively by scientists with expertise in asthma and in body weight issues may yield important clues about hormonal, genetic, and mechanical factors that influence the relationship between these conditions. Stimulation of such collaboration is the goal of this new program.

DIABETES

A major new clinical trial will test approaches to lowering risk of cardiovascular disease in adults with type 2 diabetes. The ACCORD (Action to Control Cardiovascular Risk in Diabetes) study will evaluate the effects of intense blood sugar control along with very aggressive control of blood pressure and lipids. Type 2 diabetes presents an enormous public health challenge; its many victims are highly susceptible to developing such serious consequences as heart attack, stroke, and limb amputation due to impaired circulation and an estimated 70 percent of them ultimately die of cardiovascular disease. More than 15 million Americans have diagnosed type 2 diabetes, and the number is expected to climb to 27 million by 2050; thus, if this new program uncovers a better treatment approach, its impact will be significant.

The Institute is also working to develop a program to study the causes, prevention, and treatment of cardiovascular disease in the generally younger population of patients with type 1 diabetes. Such patients who have advanced microvascular complications suffer cardiovascular disease rates 10–20 times those of the general population, and there is an urgent need to identify effective approaches to prevent or postpone this complication. Undoubtedly, some common factors contribute to the risk of cardiovascular disease in both type 1 and type 2 diabetic patients, but the differences in pathophysiology between the two diseases suggest there may also be different factors. It is hoped that a closer look at existing data regarding such factors will form the basis for development of innovative preventive interventions.

SPARK II CONFERENCE

Although this testimony has focused attention on programs and activities of immediate and obvious clinical relevance, I want to assure the Committee that the Institute is moving forward briskly on all fronts. This past October, we began revisiting a process (called SPARK, a reference to the expectation that it would ignite a new world of ideas) which had been first undertaken in 1998 to assist us in deter-

mining the best use of the funds that came our way as part of the doubling of the NIH budget. First, a working group of select scientists was assembled to assist in identifying important opportunities that the Institute should address over the next 3 to 5 years. Subsequently, a conference was held to obtain the views of representatives of three major professional societies associated with the mission of the NHLBI (i.e., the American Heart Association, the American Thoracic Society, and the American Society of Hematology). A research schema was developed that focused on five areas of opportunity: regenerative biology and replacement therapy, development and embryogenesis, immunology and inflammation, health promotion and disease prevention, and public health applications of genomics and proteomics. I expect that we will have much good news to report to the Committee in the upcoming years as the recommendations of SPARK II are implemented.

BUDGET STATEMENT

The fiscal year fiscal year 2004 budget includes $2,868 million, an increase of $76 million over the fiscal year 2003 enacted level of $2,792 million comparable for transfers proposed in the President's request.

I would be pleased to answer any questions that the Committee may have.

PREPARED STATEMENT OF DR. TING-KAI LI

I am pleased to present the President's budget request for the National Institute on Alcohol Abuse and Alcoholism (NIAAA) for fiscal year 2004. The fiscal year 2004 budget includes $430 million, an increase of $14 million over the fiscal year 2003 enacted level of $416 million comparable for transfers proposed in the President's request. Alcohol is the third leading preventable risk factor for premature death in developed countries, according to the 2002 World Health Organization report. In the United States, alcohol misuse costs society about $185 billion each year.[1]

The reason alcohol takes such a heavy toll is that its potential to cause harm extends beyond alcoholism and behaviors that lead to fatal injuries, major problems in themselves. Alcohol is not only a psychoactive substance, but also a toxin that can damage any tissue or organ in the body, unlike illegal drugs. Alcohol's toxic actions cause or contribute to certain cancers, liver and pancreatic disease, brain damage, and disturbances of the immune and endocrine systems, among other conditions. But alcohol also presents a paradox. While heavy drinking substantially raises the risk of heart disease and stroke, studies suggest that moderate drinking appears to reduce them. Thus a major contributor to disease appears to have the potential to improve certain aspects of health.

VARIATION HOLDS THE ANSWER

The explanation for the paradox lies not only in degree of drinking in terms of the quantity and the frequency of drinking, but also in differences in our biological make-up. When we can answer the question of why alcohol is harmful in some circumstances, but appears to be beneficial in others, we'll also be likely to find answers to other questions fundamental to our research: Why do only some of the people who drink, but not others, develop alcoholism or tissue damage? Why does the same medication result in sustained recovery from alcoholism in some people, but fail completely in others?

The answers lie largely in variations in our genes and the hundreds of biochemical activities they influence in our cells and, ultimately, our organs and behaviors. Different individuals and different ethnic populations can have different gene variants to yield a four-fold difference in their metabolic and behavioral responses to alcohol.

Much of our research is aimed at identifying and understanding: (1) the genes that influence how our organs and behaviors respond to alcohol, (2) the association of specific variants of these genes with specific alcohol-related outcomes, such as tissue damage or alcoholism; (3) patterns of variation in gene activity, protein activity, and metabolic activity with specific alcohol-related outcomes, and (4) how environmental factors interact with these biological factors to increase or decrease risk of alcoholism and alcohol-related problems.

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[1] National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism. *The Economic Costs of Alcohol and Drug Abuse in the United States, 1992.* Analysis by the Lewin Group, Harwood, H.; Fountain, D.; and Livermore, G. Bethesda, MD: DHHS, NIH, NIH Publication No. 98–4327 (September 1998).

Findings from this research form the basis on which we develop and test pharmacological and behavioral strategies for prevention and treatment. Through studies in humans as well as animals, a high-risk, high-technology project currently underway is developing a biosensor that will help us understand vulnerability to alcoholism and organ pathology. This unobtrusive sensor will enable us to continuously measure and integrate over time levels of alcohol and, simultaneously, measure products resulting from alcohol metabolism in a number of bodily processes.

One approach is an external skin sensor that periodically and imperceptibly inserts a probe smaller than a human hair into an individual subject's tissue or the fluid around it.

Another is to implant a microchip sensor subcutaneously. The continuous data it generates will provide valuable information about metabolic patterns of vulnerability. Clinically, alcohol levels also will reveal whether patients are complying with treatment regimens, providing clues about which treatment strategies are most effective.

CLINICAL IMPLICATIONS

Data from our basic research will enable us to do several crucial things. We will be able to provide clinicians with reliable biomarkers—laboratory tests—that will tell them which of their patients are biologically and/or genetically at risk of becoming alcoholic or of developing alcohol-induced tissue injury. Clinicians also will have the potential to predict which patients are biologically and/or genetically predisposed to respond to a specific medication for treatment of alcoholism, and which patients will respond to another.

At the same time, this research is helping us to identify molecular targets for new medications to treat both alcoholism and alcohol-induced organ damage, a pressing need in the clinical setting. As we follow the pathways from genes to physical and behavioral outcomes, we're asking where, within the many biochemical reactions that occur along the way, we can find the best molecular points at which to aim pharmaceuticals that block alcohol's actions. We also are asking if these points for intervention vary depending on variations in a person's constellation of genes, necessitating different medications or molecular targets for subtypes of the disorders.

One such point for intervention is about to be tested in human clinical trials. Our scientists used several approaches to test a hypothesis that blocking a specific receptor on brain cells—the CB1 receptor, a docking site for the brain's own version of marijuana-like substances called endocannabinoids—reduces desire for alcohol. In each approach, the CB1-receptor blocker (Rimonabant) reduced drinking. Pending results of the clinical trials, Rimonabant could become an important addition to our currently limited arsenal of effective treatments for alcoholism. We have identified another 16 compounds that are potential candidates for further development.

Our research also can help us isolate the biological mechanisms that underlie alcohol's apparent beneficial effects. Since we don't yet have clinically useful biomarkers that tell us who can benefit from moderate alcohol use and who is at risk of alcohol-related problems, and because alcohol carries with it so many well-documented risks, a recommendation to drink moderately for those who do not drink would be irresponsible at this point. If we can isolate the mechanisms that underlie whatever benefits alcohol might have, we have a chance of designing pharmaceuticals that mimic the actions of these mechanisms, but don't have alcohol's many deleterious effects.

BRAIN RESEARCH

Alcohol exerts its principal actions in the brain. It is here that heavy alcohol use results in brain-cell adaptations that lead to alcohol addiction. We're approaching this crucial area of brain research with our Integrative Neuroscience Initiative on Alcoholism (INIA). This initiative is extending beyond traditional models of collaboration to capture the potential of input from the many fields that necessarily contribute to alcohol research, including genetics, imaging, molecular biology, and behavior—each of which may use different methods and attach different significance to findings.

At the scientific level, INIA has provided its investigators with technologies and standardized animal models which ensure that the significance of findings from each field are placed in the context of alcohol research. INIA collaborations are occurring not only across fields of research, but also across universities and organizations, nationally and internationally.

More than that, INIA has created an operational structure that enables us to pursue the most productive research, relatively unencumbered by inflexible funding mechanisms. INIA's funding strategy allows us to pursue productive investigations

as they emerge, to continue them, and to discontinue those that prove to be less promising or have reached their potential. In short, INIA has removed roadblocks to progress. This is enabling us to identify the structure and function of neural circuits, networks of brain cells that work in concert as intermediaries of alcohol's behavioral outcomes.

Molecular imaging techniques are permitting INIA investigators to link alcohol-induced molecular responses with behaviors, in real time. Through computational biology, INIA researchers are creating models that predict how different brain structures and functions will respond to alcohol under different scenarios. This kind of research can help us determine optimal points for therapeutic intervention. A recent expansion of INIA will enable us to conduct translational research, to test whether neurobiological changes that occur in our animal models of alcohol-related behavior also occur in humans.

UNDER-AGE DRINKING

Drinking by children and adolescents is a concern reflected not only in our research, but also in parents and the media. Young brains are still forming nerve-cell connections, and they appear to be more sensitive to the deleterious effects of alcohol. Researchers are investigating how alcohol affects this and other processes in the developing brain, and for how long. Early indications are that adolescents who have gone through alcohol addiction and withdrawal risk long-term deficits in learning ability and memory. Research also shows that people who begin drinking at young ages are much more likely than those who begin later to become alcoholic at a later point in life.

Children and adolescents also are still developing decision-making capabilities, so important in formulating responses to environmental influences, such as peer pressure, that are powerful contributors to their choices about drinking. Almost 30 percent of 9th–12th graders surveyed report that they have had five drinks in a row at least once in the previous month.[2]

An important question in alcohol research is how different drinking patterns affect risk of developing alcohol-related problems. Heavy, episodic drinking (sometimes referred to as "binge drinking") appears to be popular among some youth—notably college students, as newspaper headlines frequently attest. A study widely publicized in the media last year estimated that 1,400 college students die each year from alcohol-related causes and that 500,000 are injured.[3]

In addition to our investigator-initiated research in this area, we have formed the Task Force on College Drinking, a collaboration between college presidents and scientists. The Task Force has released recommendations on prevention strategies, literature for various audiences, and a website, and has organized regional workshops. The Institute recently issued a research announcement calling for scientists with expertise in underage drinking to form rapid-response partnerships with colleges that request help. Episodic heavy drinking of alcohol has been ritualized and is an accepted part of life at certain celebratory events in our society, not only among youth, but also among adults. Among the questions we're asking are: How does this kind of drinking practice become ritualized in our society in spite of its deleterious consequences? How can we change the culture that leads to it?

Meanwhile, our initiative on the biological mechanisms of adolescent alcohol abuse is using imaging techniques that correlate brain structure with function and behaviors, in addition to other techniques, to reveal how alcohol affects specific brain areas, in human and nonhuman primate and rodent animal model studies. We're also asking how developmental and environmental factors and the interplay between genes and environment affect youths' choices to drink and their physical and behavioral responses to alcohol.

PREVENTION AND RISK REDUCTION

Alcohol prevention research is aimed at reducing the causes and consequences of alcohol abuse and alcoholism. For example, whether the relationship between early onset of drinking and subsequent alcoholism is one of cause and effect or the result of factors that predispose people to both those behaviors, and others, is unclear. Our investigators are studying this issue, and their findings will help us understand why people become alcoholic. Meanwhile, preventing youth from drinking and reducing

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[2] Centers for Disease Control and Prevention, *Youth Risk Behavior Survey*. http://www.cdc.gov/nccdphp/dash/yrbs/2001/youth01online.htm

[3] Hingson, R.W.; Heeren, T.; Zakocs, R.C.; Kopstein, A.; Wechsler, H. *Magnitude of alcohol-related mortality and morbidity among U.S. college students ages 18–24.* Journal of Studies on Alcohol, 63(2):136–144, 2002. (164269)

the harm it causes are essential, not only because early onset drinking predicts subsequent alcoholism, but also because of the immediate harm that alcohol misuse can cause injury, violence, early introduction into the criminal justice system, legal repercussions, derailed scholastic careers, and death, to name a few.

We are conducting studies that develop and test strategies to prevent drinking by youth of different ages and backgrounds. Particularly important among these are longitudinal studies that can tell us whether strategies that show promise among a given subgroup of youth, such as rural adolescents, are successful or can be adapted for others, such as urban youth. These studies examine the impact of a number of factors, such as school programs, parental and family influence, peer influence, alcohol advertisements, and community policies and practices.

Prevention research at NIAAA also focuses on the general population and segments with unique needs. Among them are pregnant women (and their unborn children, who are at risk of fetal alcohol syndrome) and the elderly, who may be prone to depression and dangerous interactions between alcohol and prescription drugs. One of our initiatives is determining if community-based approaches successful in preventing alcohol-use disorders in the short-term can result in long-term prevention at different life stages.

OUTREACH

Public and private partnerships are helping us send our prevention messages to the community. The Leadership to Keep Children Alcohol-Free, a prevention campaign in which the Robert Wood Johnson Foundation has joined us, has recruited 33 governors' spouses to act as spokespersons.

Other partners in our efforts to prevent under-age drinking include the National Highway Traffic Safety Administration, the Department of Justice, the Department of Education, and the Substance Abuse and Mental Health Services Administration. Our outreach efforts also target clinicians, including physician groups such as the National Hispanic Medical Association, and the National Medical Association, that serve special populations. A science-to-service program provides clinicians with information about current research, and links them with scientists who advise them on specific areas of practice, at the clinician's request. We work with States to engage their treatment providers and administrators. After exchanging information about our current research findings and the practitioners' obstacles to providing treatment, we place experts in temporary residencies in treatment programs that have identified specific areas of need. Medical schools generally aren't thorough in their coverage of alcohol-related problems, and we have produced a physician's guide to help fill the gap. Through these efforts, we promote the practical application of our research where it's most needed.

PREPARED STATEMENT OF DR. DONALD A. B. LINDBERG

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Library of Medicine (NLM) for fiscal year 2004, a sum of $316,040,000, which reflects an increase of $9,334,000 over the fiscal year 2003 enacted level of $306,706,000 comparable for transfers proposed in the President's request.

For more than 150 years one institution has been the nation's primary source of published medical information—your National Library of Medicine (NLM). Originally part of the Army, the Library became a civilian organization in the 1950s and a part of the NIH in the 1960s. Innovation in disseminating medical information has been a hallmark of the Library since the 19th century, including the first successful application of computers (40 years ago) to a large-scale bibliographic system. Today NLM not only maintains the world's largest collection of biomedical books and journals, but it has become, via the Web, a ubiquitous source of authoritative information for scientists, health professionals, and consumers around the world. Some half a billion searches of the various NLM databases are done each year.

The NLM in the 21st century is distinguished especially by two features unknown to it just two decades ago: the institution has become the leading source of human genome information and at the same time an important source of nontechnical health information for the public. The proximate source of the information that makes both these features possible is the National Institutes of Health. The NLM, through the Web operations of its National Center for Biotechnology Information, receives more than a quarter million visitors a day seeking molecular biology information ranging from DNA sequences and protein structures to the related research literature. On the other hand, the extensive health information issued by the var-

ious NIH institutes and centers forms the backbone of the MEDLINEplus information service offered to the general public.

An unusual aspect of the NLM's contemporary role that there is a direct connection between the Library's research and information programs and the defense against bioterrorism and medical and public health preparedness for disaster management and terrorist attack. To cite a few examples: genomics research databases for targeted development of drugs, vaccines, and other forms of treatment for such diseases as smallpox, anthrax, plague, Ebola, and cholera; informatics R & D related to terrorism and disaster management; training for health professionals in the use of pertinent information resources; developing experimental information resources targeted at first responders; and improving the information infrastructure so that vital data can be shared during a crisis. As to post–9/11 information services, NLM quickly placed pages on its Web site about post-traumatic stress disorder, biological and chemical warfare agents, anthrax, and other information related to bioterrorism.

TOOLS FOR SCIENTISTS AND HEALTH PROFESSIONALS

In its role as the world's largest medical library, the National Library of Medicine continues to provide access to the enormous literature of the health sciences, including even priceless historical treasures dating to the 11th century. Most medical researchers and health professionals have, directly or indirectly, availed themselves of the Library's services some time in their career; there are those who access MEDLINE/PubMed (to take one popular example) almost daily. Another heavily used information resource is GenBank (with DNA sequence data).

MEDLINE is a database of 12 million references and abstracts to the world's medical literature published since the 1960s; PubMed is the Web-based retrieval system that makes this wealth of information freely and easily searchable to health professionals and others. MEDLINE/PubMed is an evolving system. The database expands at the rate of about half a million records a year. Several years ago NLM introduced links between MEDLINE references and publisher websites so users could retrieve the full text of articles. Today, more than 3,000 of the 4,600 publications indexed for MEDLINE have such links. Another element in the evolution of MEDLINE is converting information from the 1950s, MEDLINE form, so that valuable research data, on smallpox and tuberculosis to take just two pertinent examples, will be available to today's scientists. A recent improvement is a text version of PubMed for users who require special adaptive equipment to access the web. This has had the additional benefit of making the system much more friendly for those using hand-held devices.

GenBank, on the other hand, is accessed primarily by scientists—some 50,000 of them each day. It is a collection of all publicly available DNA sequences and is thus a key element in ensuring that the flood of data resulting from research around the world, including the Human Genome Project here at home, is available for further research and for further analysis and for gene discovery. GenBank is maintained by NLM's National Center for Biotechnology Information (NCBI) and now contains more than 15 million sequences and 29 billion base pairs from over 130,000 species. These are limited to chromosome maps, gene protein products, and other relevant genetic information for human and many smaller species.

An increasingly popular NCBI service for the scientist and health professional is PubMedCentral. This is a digital archive of life sciences journal literature under which publishers electronically submit peer-reviewed research articles, essays, and editorials to be included. NLM undertakes to guarantee free access to the material; copyright remains with the publisher or the author. Creating "digital archives" is an important NLM responsibility in this electronic age.

Electronic health data standards are also part of the information infrastructure of the 21st century. Such standards are needed for safe and effective health care, efficient clinical and health services research, and timely public health and bioterrorism surveillance. NLM plays an important role in HHS initiatives to promote standardization of electronic patient data by supporting the maintenance, distribution, and linking of key clinical terminologies within the Unified Medical Language System (UMLS) Metathesaurus. As a result, these clinical terminologies are available for use throughout the United States in clinical research databases, patient care, and public health surveillance. NLM is providing funding for the development, enhancement, and distribution of several clinically specific vocabularies. The UMLS Metathesaurus provides a common distribution vehicle for such vocabularies and a mechanism for linking them to HIPAA-mandated administrative code sets, basic research vocabularies, and thesauri designed to index the scientific literature. In addition, pilot projects for testing the use of the vocabulary in different settings will be

critical for maximizing the benefit of electronic health data standards for improving patient safety, reducing costs, and enhancing effective information exchange to combat bioterrorism.

INFORMATION SERVICES FOR THE PUBLIC

Since 1998, NLM has expanded its mission beyond serving health professionals and researchers to encompass providing high quality electronic health information services for the public. To serve this audience, the Library developed a new information resource, MEDLINEplus, a Web-based service that provides integrated access to the high quality consumer health information produced by NIH and HHS components and other reputable organizations. About 1.8 million unique visitors obtained health information from MEDLINEplus in January 2003. The main features of MEDLINEplus: 600 "health topics," from Abdominal Pain to Yeast Infections, consumer-friendly information about thousands of prescription and over-the counter drugs, an illustrated medical encyclopedia and medical dictionaries, directories of hospitals and health professionals, a daily health news feed from the major print media, 150 interactive and simply presented tutorials (with audio and video) about diseases and medical procedures, and connections from the health topics to current clinical trials.

Like MEDLINE, MEDLINEplus is a constantly evolving system. Links are checked daily and new health topics added weekly. A completely Spanish-language version of MEDLINEplus was introduced in 2002 and is receiving heavy use. Early in 2003 a prototype "MEDLINEplus Go Local" system was introduced in North Carolina, a joint effort of the University of North Carolina and the NLM. This system allows MEDLINEplus users access to "NC Health Info," which contains links to local, county, and state health services in North Carolina and, conversely, users of NC Health Info can link into the detailed, authoritative health information about particular diseases and conditions in MEDLINEplus.

The NLM casts a wide net in creating and promoting MEDLINEplus, working closely with the Public Library Association and other organizations not associated with NLM's mission, as well as with the 4,700 member institutions of the National Network of Libraries of Medicine. Network librarians not only assist in identifying and evaluating information to be included in MEDLINEplus, but are of tremendous help in demonstrating MEDLINEplus locally and publicizing it.

Another major consumer information resource, ClinicalTrials.gov, was developed by the NLM on behalf of the entire NIH in response to a mandate from Congress. The database provides patients and families access to information about clinical trials and opportunities to participate in the evaluation of new treatments. The site was launched in February 2000 and currently contains approximately 7,200 clinical studies sponsored by NIH, other Federal agencies, and the pharmaceutical industry.

NLM RESEARCH AND DEVELOPMENT PROGRAMS

The Library is at the cutting edge of research and development in medical informatics—the intersection of computer technology and the health sciences. NLM has a program of grants and contracts to university-based researchers and also a cadre of in-house scientists in the Lister Hill National Center for Biomedical Communications and the National Center for Biotechnology Information. The Lister Hill Center sponsors many exciting communications research projects, such as those in telemedicine and the Visible Human Project. The NLM-supported "A Clinic in Every Home" is an especially promising telemedicine project for medically underserved rural Iowa residents to provide them with access to high quality health care. The expectation is that this system will both raise the quality of health care and lower costs. Another Lister Hill Center program is the initiative to fund projects that demonstrate the medical community's technical needs in using high-speed communications networks for critical healthcare applications, including computing in support of disaster management.

The Visible Human Project comprises two enormous data sets, male and female, of anatomical MRI, CT, and photographic cryosection images. These data sets, licensed to more than 1,700 individuals and institutions in 43 countries, are being used in a wide range of educational, diagnostic, treatment planning, virtual reality, artistic, mathematical, and industrial applications. Projects run the gamut from teaching anatomy to practicing endoscopic procedures to rehearsing surgery. NLM's AnatLine is a web-based image delivery system that provides retrieval access (even from a home computer) to large anatomical image files of various parts of the Visible Human male thoracic region, such as the heart and stomach, including 3D images.

The other major NLM component involved in R & D is the National Center for Biotechnology Information, noted above as the source of the GenBank database of DNA sequence information. NCBI is more than just assembler of genomic data, however. NCBI investigators have developed sophisticated computational tools such as the BLAST suite of programs that makes it dramatically easier for researchers to scan huge sequence databases for similarities, and to evaluate the resulting matches. Another NCBI product, Entrez, is an integrated database that allows users to easily and quickly search enormous amounts of sequence and literature information. The newest tool is the "Reference Sequence Collection" that is serving as a foundation for genomic research by providing a centralized, integrated, non-redundant set of sequences, including genomic DNA, transcript (RNA), and proteome (protein product) sequences, integrated with other vital information for all major research organisms. As genomic sequence data continues to accumulate and be made available in ingenious ways through the web, we can expect discoveries that promise future medical breakthroughs.

NLM extramural programs have an important role in supporting R & D in biocommunications. One timely example is the early warning public health surveillance system developed at the University of Pittsburgh and recently demonstrated to the President. NLM's grant program also is a key supporter of NIH's "Biomedical Information Science and Technology Initiative." The Library has expanded its support from 12 to 18 training programs at universities across the nation to train experts to carry out research in general informatics and in bioinformatics. The NLM has recently augmented each of the training programs with a "BISTI supplement" and has also funded two planning grants that will eventually lead to the development of what are called National Programs of Excellence in Biomedical Computing.

SERVING SPECIAL COMMUNITIES

The NLM has been working with the National Institute on Aging to create NIHSeniorHealth.gov. Accessible from MEDLINEplus, the new site contains information in a format that is especially usable by senior citizens. At present NIHSeniorHealth.gov contains information on topics like Alzheimer's and exercise for older adults, but it will soon be expanded to include more topics of special interest to seniors as other NIH institutes contribute to it. NLM is working on adapting special software that would allow the visually impaired to exercise control and hear Web pages read to them. This would also be a boon to some senior citizens.

The National Network of Libraries of Medicine, noted above in connection with MEDLINEplus, places a special emphasis on outreach to underserved populations in an effort to reduce health disparities. For example, there are programs to assist in remedying the disparity in health opportunities experienced by such segments of the American population as African Americans, Latinos, Native Americans, senior citizens, and rural populations. One of the NN/LM outreach efforts involves a telemedicine "connections" program for Native Americans in the Pacific Northwest conducted through the Regional Medical Library at the University of Washington.

Another highly successful NLM outreach program has been strengthening Historically Black Colleges and Universities so that they can train people to use information resources in dealing with environmental and chemical hazards. Under this program, faculty and students in more than 80 minority institutions have received such training. Through these schools, NLM is working to promote high-quality Internet connectivity and using technology for research and education.

There are other NLM programs targeting groups of citizens with special health information needs. In the past several years, the Library has made more than 50 awards to continue its HIV/AIDS-related outreach efforts to community-based organizations, patient advocacy groups, faith-based organizations, departments of health, and libraries. This program supports local programs to improve information access for AIDS patients, the affected community, and caregivers. Emphasis is on providing information in a way meaningful to the target community, and may include training in information retrieval, sending interlibrary loans, and providing Internet access.

NLM's efforts to reach special populations in need are not limited to the United States. An international partnership in which the NLM is a key player is the Multilateral Initiative on Malaria. NLM's mandate as leader of the Communications Working Group has been to leverage partnerships (at 13 installations) to create a malaria research network in Africa, enabling scientists there to have full access to the Internet and the Web as well as access to medical literature. The aim is to allow researchers, any time of the day or night, to have instantaneous Internet access that will enable them to send and receive e-mails, search for literature, interrogate data-

bases, share files and images with colleagues, and generally move to a new and more efficient way of doing collaborative research.

FUTURE PROSPECTS

NLM is responsible for acquiring, indexing, cataloging, and preserving the world's biomedical literature—in all languages and media—and for providing reference and research assistance and document delivery from this comprehensive collection. NLM also collects, processes and distributes genome sequence data through NCBI. Both of these core areas are experiencing unprecedented growth. The cost of purchasing the biomedical literature typically increases about 10 percent per year, irrespective of general inflation, and the move to electronic publishing has not diminished this rate of increase. NLM uses advanced technology to improve the efficiency of its basic operations, and contractors currently perform the majority of activities required to provide NLM's basic services.

PREPARED STATEMENT OF DR. KENNETH OLDEN

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget for the National Institute of Environmental Health Sciences (NIEHS). The fiscal year 2004 budget includes $630,774,00, an increase of $17,358,000 over the fiscal year 2003 enacted level of $613,416,000 comparable for transfers proposed in the President's request.

INTRODUCTION

Voluminous literature derived from epidemiological studies as well as human and animal experiments has shown that environmental factors play an important role in human health and disease. That is, most complex diseases arise from the interplay between genetics, environment and behavior. However, understanding of these interactions has remained grossly descriptive and the molecular mechanisms elusive. But, thanks to the rare confluence of technology breakthroughs in genomics and proteomics and the rethinking and redirection of the environmental health sciences over the past decade, the link between the environment and human health and disease can now be investigated with more rigor and specificity. For example, the sequencing of the human genome and the development of high throughput technologies to monitor the expression of genes and proteins in response to specific environmental exposures has created an unparalleled opportunity to study gene-environment interactions.

NEW INITIATIVES

Breast Cancer and Environment Research Centers.—There is surprisingly little information on the development of the normal breast. The lack of knowledge about the biological and molecular mechanisms involved in normal breast development hinders our ability to identify environmental triggers of breast cancer. How can we identify early adverse changes in breast tissue if it is not known how the tissue normally develops? To fill this research gap, NIEHS is funding a consortium centers program that will provide new information on the normal growth and development of the breast and reproductive systems, evaluate the impact of environmental exposures on the breast, and explore potential times of increased sensitivity and vulnerability of breast tissue to environmental effects. These centers represent a collaborative effort with the National Cancer Institute.

NIEHS is also continuing the effort to establish a cohort of unaffected sisters of breast cancer cases to clarify the gene-environment interactions in this disease. This cohort can be used to examine breast cancer risk in relation to factors such as endogenous hormones, growth factors and environmental contaminants, and to study these factors jointly with genes to elucidate genetic modifiers of response.

Toxicogenomics.—NIEHS developed the National Center for Toxicogenomics (NCT) to coordinate a nationwide research effort for the development of a toxicogenomics knowledge base. Toxicogenomics is a new discipline that studies how genes respond to environmental stressors or toxicants. It combines genetics (genomic-scale mRNA expression), proteomics (cell and tissue-wide protein expression), metabonomics (metabolite production) and bioinformatics with conventional toxicology to investigate the role of gene-environment interactions in health and disease. New molecular technologies, such as DNA microarray analysis and protein chips, can be used to measure the expression of thousands of genes and proteins, providing the potential to accelerate discovery of toxicant pathways and specific chemical and drug targets.

When a person is exposed to a chemical, cells in the body may respond by switching on some genes and switching off others. The on/off pattern of various genes is different for different chemicals, creating a characteristic pattern or "signature," which scientists hope will be useful in classifying chemicals and other stressors by their biological activity. This signature pattern would provide a means of predicting effects on human health from chemicals we currently know little about. Toxicogenomics seeks to use these signature gene expression patterns to go beyond the traditional toxicological tools of testing animals for adverse outcomes that might indicate toxicity.

One aim of the NCT is to create a Chemical Effects in Biological Systems (CEBS) Database. The CEBS database will contain data on global gene expression, protein expression, metabolite profiles, and associated chemical/stressor-induced effects in multiple species. With such information, it will be possible to derive functional pathways and network information based on cross-species homology. Once sufficient high quality data have been accumulated and assimilated, it will become possible to predict the toxicity of an unknown chemical by comparing its gene and/or protein expression profile to compendia of expression profiles in the database. As the field of toxicogenomics evolves, toxicogenomics databases will begin to support predictive toxicology and hazard assessment. This will help scientists predict the toxicologic impact of suspected toxicants and calculate how much of a hazard these toxicants actually represent to human and environmental health.

The pharmaceutical industry is making huge investments in this technology because of their interest in finding ways to speed up the process of toxicological assessment of new research and development products. Identifying molecular events that serve as precursors of adverse health outcomes early in the development process would eliminate much of the expense (estimated in the billions of dollars annually) associated with the development of new pharmaceutical products.

Susceptibility to Environmental Exposures.—Although reference is made to the human genome, the concept of a single genome is misleading. Each individual's genetic makeup, with the exception of identical twins, is unique. While the genomes of individuals are 99.9 percent identical, the 0.1 percent variation leaves considerable room for individual differences among the approximately three billion nucleotide base pairs that make up the human genome. However, it should be emphasized that genes are not the only factors that contribute to differences in susceptibility to environmental exposures; age or stage of development, behavior, and general health or nutritional status can have a spectacular influence. Both the genetic and age/stage of development-related aspects of susceptibility are being addressed by NIEHS.

Differences in susceptibility to environmental exposures had received little attention until NIEHS launched the Environmental Genome Project (EGP) and the Children's Environmental Health Research and Prevention Centers in 1998. There is now considerable evidence that hundreds of genes exist in the human genome that make some individuals more or less susceptible to the effects of pollutants or other environmental chemicals, contributing to everything from cancer to birth defects and Parkinson's Disease. The key objective of the EGP is to discover the alleles or genetic variants (called polymorphisms) that confer susceptibility or resistance.

The Children's Environmental Health Research and Prevention Centers were developed, in collaboration with the EPA, to explore the relationship between the timing of exposure, the stage of development and susceptibility. Because of the rapid rate of growth and development of major organ systems (e.g., the lung, brain, and heart), children are thought to be particularly vulnerable to environmental toxicants. They can be more vulnerable than adults to adverse health outcomes, and the consequences of these adverse effects are sustained throughout life, making the reduction of childhood exposures a critical component of environmental public policy.

We are also exploring the possibility of susceptibility studies in seniors. For a variety of reasons, older Americans are also more susceptible to environmental stress (e.g., the combination of poor air quality and extreme heat during the summer months). This important public health issue has received almost no attention, but dialogue is ongoing with the EPA and the National Institute on Aging about ways to include older Americans in more environmental health studies.

Parkinson's Disease Research Consortium.—NIEHS created a Parkinson's Disease Consortium Centers Research Program in 2002 because we believe that a collaborative, multidisciplinary, multi-institutional approach is required to elucidate the complex interactions between genes and environmental factors likely to be involved in the development of this devastating disease. Collectively, the three centers that make up the consortium have expertise in basic neurosciences, human genetics, clinical research, and epidemiology, and long-standing collaborative interactions with the various non-profit organizations that represent patient advocates. These sci-

entific disciplines were included in the consortium because a major impediment in Parkinson's Disease research has been that significant findings in one field were not readily disseminated among investigators in the other related fields. It is our intent to expand the Consortium Centers concept in 2004 to capture some of the outstanding activities not funded earlier.

The knowledge and technologies developed in the Institute's EGP, the Mouse Genome Centers, and the National Center for Toxicogenomics will also be made available to this cohort of investigators as they become available. For example, new Parkinson's Disease susceptibility genes and new environmental risk factors are likely to be discovered, and new mouse models of the disease are likely to be created using gene "knockout" and "knockin" technologies. These new resources will be invaluable to the Parkinson's Disease research community.

The Development of Multidisciplinary Research Teams and Novel Technologies.—The solution to complex problems often requires the collective knowledge and experience of multiple investigators and novel approaches developed at the boundary of several disciplines. While the individual investigator approach remains the cornerstone of innovation of science and technology development, translation often requires a team approach. In fact, lack of infrastructure to support the development of multidisciplinary research teams is hampering our ability to realize the benefits of the nation's expenditures for biomedical research. While the NIH has invested in infrastructure to build maps of the human genome and develop technologies for genotyping and monitoring gene and protein expression, it is the deployment of these data bases and technologies to prevent human illness that has proven to be the most challenging.

Also, the inadequacy of current analytical methods to investigate complex interactions involving genes, proteins and environmental factors has been a bottleneck in understanding the development of complex diseases resulting from such interactions. While high resolution structural analysis of proteins is critical for understanding molecular interactions between genes, or proteins and toxic chemicals, new technologies will be needed to determine how the latter disrupts structure and function of highly coordinated biological pathways or networks at the level of the cell and tissue. NIEHS has developed the Center Programs described here to catalyze the formation of multidisciplinary research teams to investigate gene-environment interactions using emerging expertise and technologies.

SUMMARY

The data generated by the studies I have described will allow for a more rational approach of gauging environmental threats, and will reduce the need to rely on default assumptions in extrapolating results from animal models to humans and in setting exposure limits. These studies will also lead to the development of high throughput technologies that could both accelerate and reduce the costs of toxicity testing of pharmaceuticals and environmental xenobiotics. This approach to understand how genes and the environment interact shifts the focus of disease management from symptom-based classification to biological causation and prevention. The objective is to provide a database that will allow for the use of precursors or molecular markers in assessment of disease states.

PREPARED STATEMENT OF DR. AUDREY S. PENN

Mr. Chairman and Members of the Committee, I am Audrey Penn, Acting Director of the National Institute of Neurological Disorders and Stroke (NINDS). I am pleased to present the President's budget request for NINDS for fiscal year 2004. The fiscal year 2004 budget includes $1,469 million, an increase of $13 million over the fiscal year 2003 enacted level of $1,456 million comparable for transfers proposed in the President's request.

The mission of NINDS is to reduce the burden of neurological disorders, that is, the many diseases that affect the brain, spinal cord, muscles, and nerves of the body. Neurological disorders cause enormous suffering and loss of life, often defying the best efforts of modern medicine. However, we are making progress in prevention and in treatment, derived from continuing advances in fundamental scientific understanding of the nervous system, which enhance the prospects for the future. Today I will touch on these points and concentrate on what NINDS is doing to expedite progress.

THE BURDEN OF NEUROLOGICAL DISORDERS

Neurological disorders can compromise the complex thinking and emotions that make us human, the routine perception and movement that we take for granted, and even the control of bodily systems that are normally beneath our awareness. Diseases of the nervous system strike at every age. Some, such as stroke, chronic pain, epilepsy, and traumatic brain injury, are among the most common of all causes of death and disability. Hundreds of less common neurological disorders take an incalculable toll on patients and families too. Also demanding attention are substantial disparities in impact by ethnic group, gender, socioeconomic status, and geography.

PROGRESS AND PROSPECTS FOR THE FUTURE

Progress in preventing and treating neurological disorders has been notable. As Dr. Zerhouni has testified previously, this year alone almost a quarter of a million fewer deaths from stroke will occur in the United States than would have been expected without advances in prevention—progress that represents the cooperative efforts of many groups, public and private. Prevention of nervous system birth defects, such as spina bifida, and genetic counseling for inherited disorders, such as Tay-Sachs disease, are also having a major impact on public health. The first acute treatments for ischemic stroke and spinal cord injury—though still far from adequate—have proven effective for reducing neurological damage. Immune therapies now reduce relapses and slow the progression of disability in multiple sclerosis. Surgical options employ implantable devices to compensate for brain circuits unbalanced by disease in Parkinson's disease and epilepsy. Enzyme therapies have brought the first successes in treating lipid storage disorders. Advances in molecular genetics and brain imaging are further augmenting clinicians' insights to diagnose and to guide therapy.

Progress is gaining momentum, with an unprecedented variety of new treatment and prevention strategies under development: drugs to home in on the molecules that cause disease, stem cell therapies to replace lost nerve cells, neural prostheses to read control signals directly from the brain, immune tolerance approaches to prevent stroke, therapies to repair or replace defective genes, and behavioral interventions to encourage the latent "plasticity" of the brain and spinal cord toward self-repair. Each of these strategies relies upon remarkable advances in understanding how the normal nervous system works and what goes wrong in disease.

A few findings from the past year illustrate this progress: Scientists studying genes discovered a mutation that causes a form of Charcot-Marie-Tooth disorder, a common disabling disease of peripheral nerves; pinpointed the site of a gene contributing to autism; and found clues about how a chromosome defect causes facioscapulohumeral dystrophy, a common form of muscular dystrophy. In animal models of human disease, themselves often the product of gene research, gene therapies have yielded encouraging results for neurofibromatosis, Fabry disease and Parkinson's. Scientists on the trail of cell therapies discovered that primitive precursor cells in the adult rat brain can respond to experimental damage by multiplying, migrating to the site of damage, and making new nerve cells, and that transplanted embryonic stem cells show promise in animal models of Parkinson's disease, stroke, and other disorders. Scientists focusing on the immune system found that a strategy, which suppresses immune reactions, prevents strokes in hypertensive rats; that an anti-cholesterol drug, the statin Lipitor, reduces symptoms in an animal model of multiple sclerosis; and that the gene defect in Batten disease may result in unexpected immune reactions, which could contribute to the devastating consequences in the brain. In research on drug treatments, the antibiotic minocycline slowed progression of amyotrophic lateral sclerosis in mice; the natural brain chemical inosine stimulated rewiring of the brain following stroke in rats; and coenzyme Q10 may slow progression of Parkinson's disease. Scientists studying new technologies developed a device that enabled rats to control a robot arm just by thinking about it; devised better ways to delivery therapeutic agents to the brain; used microarrays to monitor the activity of thousands of genes, yielding insights about brain tumors and multiple sclerosis; and for the first time, recorded activity of the human fetal brain in response to light, which may lead to better prenatal diagnostics.

EXPEDITING PROGRESS

NINDS continues to rely on the insight and ingenuity of scientists and physicians throughout the nation to seek out scientific opportunities, propose research studies, and advise on promising ideas. Since Congress began the NIH budget doubling effort, the Institute has taken a more active role in directing research. Efforts are mo-

tivated by scientific opportunity, enabled by resources, guided by extensive and inclusive planning efforts, and quality-assured through peer review. Programs target specific diseases and cross-cutting opportunities to enhance the effectiveness of research. A few examples illustrate the wide range of activities:

The NIH Parkinson's Disease Research Agenda is the pacesetter for disease-focused NINDS activities. The Agenda began in January 2000 with a working group that included Parkinson's disease researchers, patient advocates, industry representatives, and NIH scientific staff. Follow-up meetings, most recently a July 2002 "summit" called by the NIH Director, have updated priorities to reflect the changing scientific landscape and to address roadblocks to progress. Since March 2000, the Parkinson's effort has included more than 20 solicitations, more than a dozen workshops, establishment of a network of Morris K. Udall Centers, major clinical trials, and funding of the Deep Brain Stimulation Consortium. The NINDS Office of Minority and Health Research is also leading a major effort to implement the NINDS Five Year Strategic Plan on Minority Health Disparities, and developing goals specific to neuroAIDS, stroke and epilepsy. Implementation of planning efforts in brain tumor, stroke, and epilepsy are also under way. Other initiatives are focusing on diseases such as autism, muscular dystrophy, and spinal muscular atrophy, and NINDS continues to support a variety of disease-focused scientific workshops to assess current understanding, stimulate research interest, and foster collaborations.

Re-engineering the research enterprise.—NINDS has designed and conducted pioneering clinical trials to test the safety and effectiveness of interventions to prevent and treat neurological disorders. In recent years, the Institute augmented clinical trials activities with new grant mechanisms for planning trials and for pilot trials; developed procedures and increased professional staff to optimize trial design and monitoring; and created a subcommittee of the NANDS Council to provide broad advice on priorities for clinical research, including trials. This year, NINDS is beginning to supplement ongoing clinical trials to capture genetic samples for a newly established DNA and cell line repository. For the future, the Institute is exploring options to create a network of physician-investigators to carry out clinical trials. Such a program might speed trials, minimize costs, enhance accessibility for patients, facilitate the recruitment of a diverse spectrum of participants, improve feasibility of trials for rare diseases, and accelerate the transfer of results to practice in community settings.

A highlight of the clinical trials program is an innovative trial of neuroprotective drugs for Parkinson's disease, that is, drugs which slow disease progression rather than just temporarily improving symptoms. The Institute reached out widely to academia and industry, here and abroad, for suggestions of possible drugs, and developed a rigorous evaluation process, which has selected the most promising drug candidates. A network of more than 40 clinical sites, with central statistical and data coordination, has been established to carry out the trial. NINDS is working closely with voluntary groups to recruit patients. The first pilot studies may begin this spring.

Translational research is another major focus of cross-cutting efforts. NINDS has a long history of translational research, which moves fundamental discoveries about the brain and disease toward therapies and clinical trials. Advances in neuroscience are yielding increasing opportunities for translation, and NINDS responded in July 2002 by launching a comprehensive program to foster translational research. Essential to this program are peer review criteria tailored to the needs of translational research, milestone driven funding, and training a cadre of investigators to carry out translational research. The goal is to provide an environment where coalitions of basic scientists and clinicians can design and carry out preclinical studies required to bring therapeutic candidates to the point where clinical studies can begin.

New pathways to discovery.—Several NINDS programs are exploring new avenues for discovery. NINDS has established a goal of identifying small molecules that are active in the nervous system and show promise as therapeutic candidates, diagnostic agents, or research tools. In 2002, the Institute established a consortium to test more than 1000 drugs, most previously approved by the U.S. Food and Drug Administration (FDA) for other conditions, against 29 rapid laboratory assays (tests) related to neurodegenerative diseases. The best candidate chemicals are moving to further testing in animal models through an NINDS supplement program. NINDS has also awarded a contract for a high throughput screening (HTS) center, and is soliciting proposals for the development of assays for HTS. HTS rapidly tests thousands of chemicals to find lead compounds for drug development. In another effort, a contract-based approach to therapeutics development for spinal muscular atrophy will test a new model that might apply to other diseases. The NIH Molecular Library Roadmap Project will speed the discovery process for drugs and chemical research tools by providing access to information databases and to potentially useful

compounds. The Institute has also established a facility to provide researchers access to microarray technology, which allows simultaneous monitoring of the activity of thousands of genes in health and disease. Stem cell research remains a high priority for the Institute. NINDS has provided supplements for grantees to pursue stem cell research, and joined with other components of NIH in stimulating this research and targeting aspects critical for the nervous system. An NINDS intramural investigator will lead a new NIH facility to characterize the available approved lines of human embryonic stem cells.

Research teams of the future.—Increasingly, progress against neurological disorders requires cooperation among multi-disciplinary teams of investigators. NINDS is enhancing the opportunities for team approaches with general programs to support common resources and specific initiatives tailored to areas such as Parkinson's disease, stroke, autism, muscular dystrophy, spinal cord injury and health disparities. The Institute is also addressing critical training needs in areas such as translational and clinical research. In the NIH Intramural program, the John Edward Porter Neuroscience Center will bring together scientists from ten NIH components that focus on the brain.

CONCLUSION

Neurological disorders have always challenged the best efforts of medicine. The intricacy of the brain is awesome, its workings are elusive, and an extraordinary variety of disorders affect the nervous system. Furthermore, the brain and spinal cord are difficult to access, sensitive to intervention, and reluctant to regenerate following damage. However, building on advances in basic science, progress is improving peoples' lives, and prospects for the future are even more encouraging. We are working to engage the best minds in the nation and provide them with the resources they need to devise ways to prevent, treat, or, ultimately, cure neurological disorders. Thank you.

PREPARED STATEMENT OF DR. RODERIC I. PETTIGREW

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB). The fiscal year 2004 budget includes $282,109,000, an increase of $3,838,000 over the fiscal year 2003 enacted level of $278,271,000 comparable for transfers proposed in the President's request.

The NIBIB's mission is to lead the development and application of breakthrough technologies in the physical and engineering sciences to facilitate an improved fundamental understanding of complex biological processes. This research agenda will dramatically advance the Nation's health care by improving the detection, management, understanding and, ultimately, the prevention of disease. Health care and technology have long been linked in the United States. Today, cardiac pacemakers, mammograms, sustained release medications, and artificial hips are but a few examples of how biomedical imaging and bioengineering are transforming health care.

In September 2002, I began my tenure as the first Director of the NIBIB. I assumed my role during a time when the landscape of conducting biomedical research is changing. It is this altered landscape, wherein the most efficacious medical advances depend on multidisciplinary findings obtained from researchers working together at the interface between the biological and quantitative sciences, that led to the creation of the NIBIB. This new environment, combined with recent budgetary increases, visionary predecessors, the rapid pace in technology development, and high-quality investigator-initiated research, has allowed the NIBIB-just in its second year of operation-to establish a strong research foundation on which to capitalize. To illustrate these points, my testimony will highlight recently achieved milestones, outline research plans and directions, and describe areas of progress and opportunity.

MILESTONES TO SUCCESS

The NIBIB, the newest Institute at the National Institutes of Health (NIH), was established by law December 29, 2000, and received its first appropriation and grant funding authority in fiscal year 2002, just 15 months ago. Since its establishment, NIBIB staff have achieved significant milestones. In fiscal year 2002 the NIBIB funded approximately 300 research applications, participated in approximately 170 extramural symposia, planned 16 NIH-based symposia and workshops, served as lead on 5 trans-NIH initiatives, and collaborated on 4 trans-NIH programs.

Additional milestones have been achieved in fiscal year 2003. In January, the NIBIB held the first meeting of its National Advisory Council. The Institute has also built a solid research infrastructure through the release of numerous basic and applied research solicitations in promising areas of scientific investigation, including tissue engineering, advanced biomaterials, image-guided interventions, low-cost medical imaging modalities, biosensor technology, and cellular and molecular imaging.

The NIBIB has successfully fostered extensive linkages and collaborations with other NIH Institutes and Centers, Federal agencies, academic institutions, private industry, and scientific societies. As examples, the NIBIB administers and participates in the Bioengineering Consortium (BECON), an NIH-wide consortium dedicated to promoting and coordinating bioengineering research across the NIH. The NIBIB and the National Science Foundation are collaborating with the National Academy of Engineering-a private, independent, nonprofit institution-on a project entitled "Engineering and the Health Care System." This study focuses on ways to harness advances in engineering applications to improve health care delivery. The NIBIB will collaborate with the National Institute of Diabetes and Digestive and Kidney Diseases to develop a program for monitoring pancreatic insulin cell failure in diabetes. This would constitute a significant advance in diabetes research.

THE NIBIB RESEARCH PORTFOLIO

In December 2002, the NIBIB officially launched its strategic planning process with an interactive workshop entitled "Future Research Directions." This workshop helped identify high-priority research focus areas and associated high-impact projects and technologies that could contribute significantly to biomedical research and global healthcare needs. Areas identified as highly relevant to NIBIB's mission include image-guided interventions, cellular and molecular imaging, computational biology, biosensor technologies, optical imaging technologies, and regenerative medicine. The Institute is now poised to realize the promise within these areas of opportunity.

ADVANCED TECHNOLOGIES

Biomedical imaging and bioengineering are interdisciplinary fields that require collaborations not only among imagers and engineers, but also with biologists, chemists, mathematicians, computer scientists, and clinicians of all specialties. Today, the imaging and engineering sciences are essential for improved understanding of biological systems, detecting and controlling disease, and enhancing human health. Recent advances in these fields have enabled the diagnosis and treatment of various diseases using increasingly less invasive procedures. Benefits associated with minimally invasive imaging applications include quicker and more accurate diagnoses leading to improved patient outcomes at reduced costs. Minimally invasive image-guided interventions now serve as powerful tools in the operating room and can be applied to surgical procedures in urology, oncology, neurosurgery, ophthalmology, cardiology, and orthopedics. However, these techniques are in relatively early stages of development. A goal of the NIBIB is to further establish and validate minimally invasive image-guided therapies as standards for patient care and to support additional research in therapeutic areas where minimally invasive technologies do not yet exist. The NIBIB also has initiatives underway to encourage investigator-initiated research for tracking anatomical targets and instruments and for developing steerable devices, including catheters, endoscopes, and needles. A goal is to develop theses techniques so that they may be used to routinely identify disease at its earliest stages, even before symptoms arise. At that point, treatments can be instituted to cure the disease or preempt any serious consequences.

The combination of image-guided therapies with genomics and proteomics, has given researchers the capacity to develop new molecular probes and targets for disease detection, and to immediately direct treatment to the diseased site. By studying how a person's genetic blueprint is expressed through proteins, and how these proteins differ in healthy and diseased cells, researchers will be able to develop therapies tailor-made for an individual. As a first step towards "personalized medicine," NIBIB researchers are investigating tiny "barcoded" metal particles as a method for analyzing proteomes-the complete set of an organism's proteins. Advances in miniaturized devices not only have the potential to identify and characterize new proteins, but to advance the rapid screening of multiple compounds in the drug development process.

Molecular imaging provides a way to monitor cellular activities in normal and diseased states. The development of novel imaging technologies, combined with new or enhanced probes that bind to defined cellular targets, will allow this technique to

be more broadly applied to biomolecules that are known indicators of a diseased state, such as an enzyme that may be overexpressed in a specific tumor. For example, NIBIB researchers have developed artificial fluorescent agents, called quantum dots, that glow and act as cell markers when bound to certain cancer cells. Further testing of these agents in animal models of cancer will determine their utility as effective imaging agents for the early detection of cancer in humans.

BIOINFORMATICS AND COMPUTATIONAL BIOLOGY

Advances in bioinformatics and computational biology have been identified as one of the areas of greatest need, and one of the areas having the greatest potential for positive impact on the universe of medical science and health care. In recognition of the critical role these disciplines play in biomedical imaging and bioengineering, NIBIB supports fundamental research in computing technology, the targeted development and application of new biocomputing tools, and technologies that provide structural and functional data at the cellular level. Areas of NIBIB interest include the development of high performance computing and visualization methods applicable to the modeling of biological systems, the utilization of medical imaging data in computational modeling of biological systems and human physiology, the development of algorithms and software for the manipulation and analysis of imaging data, and computer modeling of tissue mechanics. Our goal is to advance an understanding of the integrated function of biological systems through the development and application of computational models, and to apply these models to the design of novel treatments and therapeutics. In support of this goal, a NIBIB researcher is developing a brain-computer interface (BCI) system that acquires and analyzes brain signals to create a communications channel directly between a person's brain and a computer. BCI technologies can allow people who are completely paralyzed to express wishes to caregivers and to use computer programs.

NANOTECHNOLOGY: SENSORS FOR MEDICINE

The term nanotechnology is used to describe many types of research at the atomic, molecular, or macromolecular level-research where the characteristic dimensions are less than one-thousandth of the diameter of a human hair. Biosensors are nanoscale devices that detect, monitor, and transmit information about a physiological change, or about the presence of various chemicals, gases, or biological materials (bacteria and viruses). Laboratory diagnostics used in hematology, clinical chemistry, pathology, and microbiology already employ sensor technologies to perform simultaneous measurements for hundreds, maybe thousands, of substances in urine, blood, saliva, sweat, and interstitial fluids. The NIBIB has an active research program in sensor technologies and is expanding this area of research.

Knowledge gained through NIBIB-supported advances in nanotechnology, particularly in the areas of biosensors and molecular imaging, will be further leveraged for the development of sensors that can be applied to other critical research areas. For example, NIBIB researchers are adapting highly sensitive and selective biosensor arrays to provide a fingerprint for the identification of harmful bacteria and environmental health hazards. Future NIBIB efforts being planned in nanotechnology and sensors focus on the development of low-cost, miniaturized, integrated sampling detector systems for field use, including the development of systems that provide "detect-to-warn" capabilities, and that enable the rapid and accurate verification of exposure to harmful environmental agents.

MULTIDISCIPLINARY RESEARCH TEAMS OF THE FUTURE

The era of the solo independent investigator is passing. Our research culture must be redirected to the formation of teams that span academic departments and scientific disciplines. Their formation is critical to the development and validation of new technologies to aid in disease detection, treatment, and prevention. Therefore, a major goal of the NIBIB is to catalyze team science through initiatives that encourage multi-organizational and multidisciplinary teams. Programs differ from traditional NIH opportunities as they require collaborative efforts between quantitative and biomedical researchers. These will support institutional needs, infrastructure development, and the costs associated with making team science viable and attractive to academic institutions. Within a given area, specific clinical problems-such as our current effort to image pancreatic beta cell function in diabetes-will be identified to serve as a catalyst to drive the formation of the research team. The value in catalyzing team science lies not only in strengthening research capacity, but in fostering the formation of research teams among disciplines where they previously have not naturally formed.

In conclusion, the NIBIB is dedicated to promoting the development of emerging technologies and establishing opportunities that will encourage the necessary interdisciplinary collaborations to advance biomedical and global health care priorities. I would be pleased to respond to any questions that the Committee may have.

PREPARED STATEMENT OF DR. JOHN RUFFIN

Mr. Chairman and members of the Committee: I am pleased to present the President's budget request for the National Center on Minority Health and Health Disparities (NCMHD) for fiscal year 2004, a sum of $192,724,000, which represents an increase of $7,010,000 over the comparable fiscal year 2003 appropriation.

Despite improvements in the overall health of the general population, over the past decade, African Americans, Hispanics, American Indians, Alaska Natives, and Asians and Pacific Islanders the fastest growing communities in this country and the urban and rural poor, continue to suffer an unequal burden of death, disability, and disease.

With the goal of addressing health disparities through science, the Congress enacted Public Law 106–525, the Minority Health and Health Disparities Research and Education Act of 2000, to establish the NCMHD. The mission of the Center is to promote minority health and to lead, coordinate, support, and assess the National Institutes of Health's (NIH) effort to ultimately eliminate health disparities. I am grateful to the Congress for its wisdom in creating the NCMHD so that America can be more responsive to its increasingly diverse and complex health and human services needs. And, I thank you for your ongoing support of the Center. I also want to thank Dr. Elias Zerhouni, Director of the NIH, and the Directors of the NIH Institutes and Centers (ICs) and Offices for all of their cooperation and continued commitment to making the elimination of health disparities a top priority for the NIH.

In January 2003, the NCMHD celebrated its second anniversary. The staff at the NCMHD has been diligent, working hard to make the priorities envisioned for the Center by the Congress a reality. Today, I am happy to report to you the highlights of our accomplishments.

TRANS-NIH STRATEGIC PLAN AND BUDGET

The NCMHD has worked together with the Director of the NIH and the Directors of the other ICs at the NIH, to develop the first comprehensive *NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities.* This Plan, which was developed with substantial stakeholder input from the health disparities populations, has three main goals—research, research infrastructure, and community outreach through information dissemination and public health education. This is an evolving document, that will be updated each year, and it includes current NIH activities and future plans to: address the health disparities; build a culturally competent cadre of biomedical and behavioral investigators; and increase the number of minority clinical and basic medical scientists who are essential to the success of our efforts. The Plan will be posted for public comment on the NCMHD website at www.ncmhd.nih.gov.

NIH FISCAL YEAR 2001 ANNUAL REPORT ON HEALTH DISPARITIES RESEARCH

The NCMHD also collaborated with the other ICs to develop the *NIH fiscal year 2001 Annual Report on Health Disparities Research,* which highlights the NIH's activities, and describes the progress emanating from the NIH's research strategies, structures, processes, and programs to ultimately reduce and ultimately eliminate health disparities.

NCMHD PROGRAMS

As authorized by the Congress, the NCMHD has established its three core programs, which have been successfully launched with substantial assistance from the other NIH ICs. The Centers of Excellence in Partnership for Community Outreach, Research on Health Disparities, and Training (Project EXPORT) Program supports the conduct of research, research training, and community outreach activities in the field of health disparities at Centers of Excellence. The Research Endowment Program is designed to build minority health and other health disparities research capacity at Health Resources and Services Administration (HRSA) Section 736 Centers of Excellence. The NCMHD has established two distinct extramural Loan Repayment Programs to increase the participation of health professionals in health disparities research and to increase the participation of individuals from disadvantaged backgrounds in clinical research. The Center also administers the Research

Infrastructure in Minority Institutions (RIMI) Program to provide support for institutions that enroll a number of students from minority health disparity populations to develop and enhance their capacity and competitiveness to conduct biomedical or behavioral research. By expanding the infrastructure of institutions committed to health disparities research and supporting the education and training of racial and ethnic minorities, as well as the medically underserved, these programs will provide sustained effort aimed at eradicating health disparities.

NCMHD CO-FUNDED RESEARCH

The NCMHD also supports research through collaborative agreements with other NIH ICs and HHS agencies, for example the: *Racial and Ethnic Approaches to Community Health Program (REACH 2010)* at the Centers for Disease Prevention and Control (CDC); *Excellence Centers to Eliminate Ethnic/Racial Disparities Program (EXCEED)* at the Agency for Healthcare Research and Quality; *Jackson Heart Study* at the National Heart, Lung and Blood Institute (NHLBI); *Appalachia Cancer Network and Native Hawaiian Cancer Awareness Research & Training Network* at the National Cancer Institute (NCI); *National Latino and Asian American Study* at the National Institute of Mental Health, and *Tribal Epidemiology Centers Program* at the Indian Health Service.

Through these and many other co-funded projects the NCMHD works to: pilot new health disparities programs; improve recruitment and retention of racial and ethnic minorities in clinical trials; and provide competitive supplements to expand the focus of existing research programs.

NIH HEALTH DISPARITIES RESEARCH

Along with the NCMHD, all of the ICs at the NIH actively support health disparities research within their categorical missions. Let me provide a few illustrative examples:

The NHLBI supports the Jackson Heart Study, co-sponsored with the NCMHD, to address the cardiovascular health of African Americans; the Strong Heart Study, directed at cardiovascular disease risk factors and development in American Indians; the Multi-Ethnic Study of Atherosclerosis, which is examining the development and progression of subclinical disease in a multi-ethnic and predominately minority population; the Family Blood Pressure Program, which is identifying major genes associated with high blood pressure in a predominately African American population; studies aimed at identifying genetic and other biological factors that increase susceptibility to hypertension-related injury and damage; and programs examining genetic factors associated with asthma in minority populations.

To lead the NCI's efforts to examine the causes of cancer health disparities, develop effective and sustainable interventions to eliminate them, and actively facilitate their implementation across the cancer continuum, the NCI established the Center to Reduce Cancer Health Disparities. Among the NCI's other major initiatives are the expansion of public, private, academic, and community-based partners to increase enrollment of minorities in clinical treatment and prevention trials and to investigate the socioeconomic, cultural, health system related, and other causes of disparities in cervical cancer mortality. The NCI also has established interdisciplinary research Centers for Population Health and Health Disparities to better understand the interaction of determinants of cancer and the behavioral and biologic factors that contribute to them, and the Institute has expanded and improved the efficiency and utility of the Surveillance Epidemiology End Results Program on several fronts.

The National Institute of Allergy and Infectious Diseases (NIAID) continues to focus on those research areas that have a major impact on health disparities by supporting: the Innovation Grant Program, which fosters exploratory investigator-initiated HIV vaccine research at the early stages of concept development; the Legacy Donor Registry Project, which supports efforts to increase organ donation in minority populations; Genetic studies in African-American kidney transplant recipients regarding tissue (organ) rejection; Autoimmunity Centers of Excellence, which evaluate immunotherapies for Systemic Lupus Erythematosus (SLE) and Scleroderma; the Inner City Asthma Consortium, which evaluates the safety and efficacy of promising immune-based therapies to reduce asthma severity and prevent disease onset in minority children in inner city dwellings; and Hepatitis C Cooperative Research Centers, which study factors that contribute to resistance to treatment in African Americans and disease outcome in Alaska Natives and Hispanics.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has established its Office of Minority Health Research Coordination to help implement its strategic plan for health disparities. The Institute places high priority on

supporting studies of many diseases, including type 2 diabetes, hepatitis C, and kidney disease, which disproportionately impact the health of minority populations. Recently the Diabetes Prevention Program showed that modest improvements in diet and exercise could dramatically decrease the incidence of type 2 diabetes in those at risk, the benefits of which extend to all racial and ethnic groups. American Indian and Alaska Native communities have the highest rates of diabetes in the world. Using the network of Tribal Colleges and Universities, the NIDDK Diabetes-Based Science Education in Tribal Schools Program is developing supplemental curricula for Tribal elementary, middle and high schools to instruct students about lifestyle changes that can dramatically reduce the risk of diabetes. The NIDDK also has initiated the National Kidney Disease Education Program, initially targeting cities with African-American populations showing high incidence of chronic kidney disease.

Since the National Institute of Child Health and Human Development (NICHD) launched its national "Back to Sleep" campaign in 1994, the Sudden Infant Death Syndrome (SIDS) rate has fallen by more than 50 percent. Even though the death rates from SIDS have declined at about the same rate for White and African-American infants, a disproportionate number of African-American infants are still lost to SIDS. To begin closing this gap, the NICHD enlisted the help of the Alpha Kappa Alpha sorority, the National Coalition of 100 Black Women, and the Women in the NAACP to conduct a series of "summit" meetings in three U.S. cities with high rates of African-American SIDS deaths. These summits will help develop strategies and create an infrastructure for establishing community-based programs to further reduce SIDS among African-American infants. The NICHD also is developing outreach activities and products that encourage American Indian/Native American communities to place babies on their back to sleep.

CONCLUSION

The NCMHD is working together with the other ICs at the NIH to ensure that all Americans have an opportunity to lead long, healthy, and productive lives. I am grateful to the Congress for giving the Center a unique opportunity to bring together the expertise of health professionals, researchers, businesses, communities, academia, public health agencies, and government to eliminate health disparities. It's going to take all of us working together to build a healthy America.

PREPARED STATEMENT OF DR. PAUL A. SIEVING

Mr. Chairman an members of the Committee: I am pleased to present the President's budget request for the National Eye Institute (NEI) for fiscal year 2004. This budget includes $648 million, an increase of $16 million over the fiscal year 2003 enacted level of $632 million comparable for transfers proposed in the President's request.

It is my privilege to be here as the Director of the NEI and tell you about progress laboratory and clinical scientists are making in combating blindness and visual impairment and about the unique opportunities that exist in the field of vision research.

GLAUCOMA RESEARCH

Glaucoma leads to blindness from damage to the optic nerve of the eye. Glaucoma is often, but not always, associated with increased pressure within the eye caused by inadequate drainage of aqueous humor, the fluid within the eye that nourishes the cornea and lens. Results from two important clinical trials were reported during this past year. Investigators conducting the Ocular Hypertension Treatment Study found that eye drops used to treat elevated pressure inside the eye can be effective in delaying the onset of glaucoma. The study identified several significant risk factors that were associated with the development of glaucoma in study participants. These included personal risk factors, such as older age and African descent, as well as ocular risk factors, such as higher eye pressure and certain characteristics of the optic nerve and cornea. These results mean that treating people at higher risk for developing glaucoma may delay or possibly prevent the disease.

In a separate study researchers conducting the Early Manifest Glaucoma Trial, which was designed to compare the effect of immediate therapy to reduce pressure inside the eye with late or no treatment on the progression of newly detected open-angle glaucoma, found that progression was less frequent in the treated group (45 percent) than in the control group (62 percent), and occurred significantly later in

treated patients. This finding demonstrates definitively that treatment to lower pressure inside the eye can slow glaucoma damage and subsequent vision loss.

Continuing the progress in the genetics of glaucoma reported last year by the finding of a new gene mutation that caused a form of adult-onset glaucoma, scientists recently reported identification of a human gene that is linked to a disease known as "low-tension" glaucoma. This form of glaucoma has the characteristic pattern of optic nerve degeneration but the elevation in pressure within the eye normally associated with this pattern of damage is not evident on clinical examination. The gene that was identified produces a protein that is expressed in a number of tissues including the brain and retina and is believed to have a significant neurological function. The identification of genes associated with glaucoma provides a tool to study the biochemical pathways leading to optic nerve degeneration, as well as giving insight into designing neuroprotective strategies. Additionally, NEI sponsored a meeting on ganglion cell and optic nerve degeneration that brought together laboratory and clinical scientists studying glaucoma and those studying other neurodegenerative diseases to explore common mechanisms of nerve cell damage and potential methods of protection.

RETINAL DISEASE RESEARCH

The retina is the transparent, light-sensitive tissue that lines the back of the eye. Diseases and disorders of the retina and its blood vessels account for much of the blindness and visual disability in this country. An important barrier to therapeutic intervention in human retinal disease is the identification of the gene or genes that cause vision loss. Visual loss and the degenerative and other changes in the retina are largely linked to rod and cone photoreceptors, the light-sensing nerve cells in the retina.

Scientists have recently undertaken a comprehensive genetic analysis of rod photoreceptors, the most abundant sensory neuron in the retina, in order to identify all the possible genes expressed in these cells. Rod cells play an essential role in the visual pathway and may be especially vulnerable to any genetic defect involving the retina or other visual centers. For many identified retinal disease genes, a photoreceptor gene is mutated and its product is altered due to the mutation. Work is progressing on completing a database that will simplify the identification of candidate retinal disease genes, and many new genes in rod photoreceptors have already been identified.

Scientists have identified a mutation in a gene on the X chromosome that normally is associated with a form of retinitis pigmentosa (RP) that causes a progressive loss of rod photoreceptors in the peripheral retina and results in blindness in adulthood. This mutation was also reported to cause a unique type of degeneration in the macula, in a particular family. Further study may help us understand how this mutation specifically targets the macula and causes this unique loss of cones. This may lead to an understanding of the mechanisms of damage in other forms of macular degeneration and perhaps to the development of the means to prevent this type of damage to the macula.

The NEI is also funding studies on ocular albinism, a set of hypomelanotic diseases and conditions that are characterized by deficient cellular production of the pigment melanin. Deficiency in this pigment causes a cosmetic loss of ocular and skin pigmentation, but more importantly, it limits the development of vision in infants and children by fundamentally altering the connections between the eye and the brain. Recently the OA1 gene, which is associated with most cases of the disease, was identified. The form of the disease associated with OA1 is an X-linked or hereditary blinding eye disease that primarily affects boys at an early age. Although the cause or causes are unknown, misrouting of the neurons that go from the retina to the brain is involved. Understanding the causes of the abnormal neural cell axon guidance in ocular albinism may help us understand the fundamental neurobiology that underlies this disease and represents an important research initiative for the NEI.

CORNEAL DISEASE RESEARCH

NEI-supported scientists have also made progress against blinding diseases of the cornea. The cornea is the transparent tissue at the front of the eye that plays an important role in refracting or bending light to focus visual images sharply on the retina. Because the cornea is the most exposed surface of the eye, it is especially vulnerable to damage from injury or infection. One such infection is ocular onchocerciasis, commonly known as river blindness. Although river blindness is rare in developed countries, it is the second leading infectious cause of blindness in the world. This infection occurs when a nematode worm infects the cornea. Researchers

have found that development and growth of the worm depends on a bacterium that lives within it. They found that the blindness associated with the infection was due to the reaction of the patient's immune system to the bacterium and not to the worm. The scientists discovered that an antibiotic that killed the bacterium also caused the death of the worm but without causing blindness. Further development of this treatment could revolutionize treatment of river blindness throughout the developing world.

CATARACT RESEARCH

Although cataract treatment in this country is one of the most successful of all surgical procedures, development of non-surgical approaches to preventing or treating cataracts remains an important area of research, because of the potential that it holds for reducing costs to the Medicare system and improving the quality of life of our senior citizens. A cataract is an opacity of the eye's normally clear lens that interferes with vision. Age-related cataract formation is believed to result from the complex effects of aging on normal physiological processes. Because the end-result, cataract formation, is in most cases far removed in time from the initial insult, exacting a cause and effect relationship has been difficult. Lens transparency results from the very high concentration of soluble proteins, the crystallins, within a specialized lens fiber cell. During aging and cataract formation, soluble lens crystallins tend to combine or aggregate into large complexes that cause light to scatter. NEI-sponsored researchers have found that alpha-crystallin, which normally protects the lens by binding to other proteins, may itself become the vehicle for the aggregate formation that accelerates cataract formation. Additional research in this area may provide the means for clinicians to intervene prior to the formation of a clinically evident cataract.

Other scientists are attempting to determine the genes that control one of the earliest events in the development of the eye, the development of the lens. Scientists studying lens development have identified a master gene that controls the expression of a number of other critical genes. Two of these critical genes that have recently been discovered. Without these two genes, the development of the lens is stopped and crystallin-synthesizing cells fail to form. These findings add to our understanding of the overall control of lens and eye development and may ultimately enhance our knowledge of the molecular basis of congenital diseases of the eye, thereby opening the possibility of future interventions.

STRABISMUS, AMBLYOPIA, AND VISUAL PROCESSING RESEARCH

The most frequent causes of vision loss in our children are strabismus, a misalignment of the eyes, and the development of amblyopia, or lazy eye. Strabismus results in diseases in which visual processing is abnormal. Amblyopia can result from this misalignment or from unequal refraction between the eyes. NEI-supported scientists have found that eye drops used to treat amblyopia work as well as the standard treatment of patching the eye. This research finding may lead to better compliance with treatment and improved quality of life in children with this eye disorder. Patients continue to be followed in this study to better assess the long term effects these treatments have on visual acuity.

Recent work by NEI-sponsored researchers has helped our understanding of nerve cell regeneration. Following injury or disease, neurons in the central nervous system (CNS) have a limited regenerative capacity, unlike nerve cells in the peripheral nervous system.

Nerve cells typically have two types of extensions that arise from their cell bodies. Axons are normally quite long and extend over considerable distances. Dendrites are much shorter and extend short distances from the cell body. The inability of CNS neurons to regenerate is due to the failure of their axons to re-grow. These scientists found that axon growth may be due to a factor within the nerve cell itself rather than in the surrounding environment and may be regulated by signals from other nerve cells. Further research may allow discovery of the signals that switch neurons back to the axonal growth mode to repair damage to nerve tissue from injury or disease.

HEALTH DISPARITIES

Scientists recently reported the prevalence of glaucoma in a population-based study conducted among 4,774 Mexican American adults residing in two communities in Arizona. Glaucoma prevalence rates have been reported previously for white and African American adults, but no similar studies have been conducted among the U.S. Hispanic population. The prevalence of open-angle glaucoma in this Mexican American population was intermediate between the high rates reported for African

Americans and the lower rates reported for whites. Of those diagnosed with glaucoma, only 38 percent were aware they had the disease. The prevalence of glaucoma increased rapidly with age and was the leading cause of bilateral blindness in this population. This information will allow health educators to create additional glaucoma awareness campaigns to increase awareness of the importance of glaucoma treatment in the Mexican American population, thereby allowing eye care providers to identify and treat those at greatest risk so that blindness can be prevented.

PROGRAM INITIATIVES

Diabetic retinopathy is a potentially blinding complication of diabetes characterized by the uncontrolled growth of fragile new blood vessels in the retina that may leak fluid and blood threatening vision. It is the leading cause of new cases of blindness in working age adults in the United States. Macular edema secondary to diabetic retinopathy is also a major cause of visual loss in patients with diabetes. The NEI is developing a clinical research network of core centers and participating clinics that will help satisfy the need to evaluate promising new approaches to treat diabetes induced retinal disorders and to investigate other approaches as they become available. This network approach will provide a framework for rapid initiation of important studies, efficient use of pooled clinical expertise in idea generation and protocol development, and efficient use of central resources for data management, quality control, and endpoint evaluation.

The NEI is also planing to increase the pace of research in age-related macular degeneration (AMD) prevention and treatment by supporting a wide array of laboratory and clinical studies. AMD is the leading cause of severe vision loss in older persons in the United States, and it will have an increasingly important social and economic impact as the population ages. These studies may range from pilot work to the establishment and implementation of clinical research networks. It is anticipated that a network approach to AMD clinical research will hasten development of the more successful therapies for the treatment or prevention of AMD.

The NEI is also undertaking a major effort to reinvigorate the intramural research program and enhance resources to neurodegenerative and genetic forms of vision loss. Ocular genetics research has demonstrated that many common eye diseases have complex genetic and environmental etiologies that must be understood before innovative biological treatments can be designed. NEI is working on a new laboratory program devoted to complex human eye disease to hasten progress in this area.

Mr. Chairman that concludes my prepared statement. I would be pleased to respond to any questions you or other members of the committee may have.

PREPARED STATEMENT OF DR. ALLEN M. SPIEGEL

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for fiscal year 2004, a sum of $1,670,007,000, which reflects an increase of $66,846,000 over the comparable fiscal year 2003 appropriation. The fiscal year 2004 budget comprises $1,820 million which includes $150 million ($100 million in fiscal year 2003) for the Special Appropriation for Research on Type 1 Diabetes through Public Law 107–360. The NIDDK transfers some of these to other institutes of the NIH and to the CDC. Adjusted for these mandatory funds, this is an increase of $48 million over the fiscal year 2003 enacted level of $1,622 million comparable for transfers proposed in the President's request. The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report, which compared our fiscal year 2002 results to the goals in our fiscal year 2002 performance plan.

OBESITY RESEARCH

I appreciate the opportunity to testify on behalf of the NIDDK, which supports research on a wide range of chronic, debilitating diseases. Many of these diseases, including type 2 diabetes, nonalcoholic fatty liver disease, gallstones, end-stage kidney disease, and urinary incontinence, are caused, directly or indirectly, by obesity. Data from the Centers for Disease Control and Prevention documents that obesity is growing at an alarming rate in both adults and children, and that it disproportionately affects minorities. Recent results from the Framingham Heart Study indicate that obesity cuts six to seven years off of life, comparable to the effects of smoking. The 2001 *Surgeon General's Call to Action to Prevent and Decrease Overweight*

and Obesity reports that each year, it costs this country an estimated $117 billion in health care related expenditures.

We must approach obesity, not as a cosmetic or moral problem, but rather as a health problem. To address this problem, research is vital, and the NIDDK and the National Institutes of Health are formulating a bold and coordinated research plan. Obesity and its associated diseases result from complex interactions of biologic and environmental factors. The environmental factors include social, demographic, and economic changes that encourage people to eat more food than necessary to meet their energy requirements, and discourage physical activity that would increase their energy expenditure. These environmental factors disproportionately affect individuals who are biologically more susceptible to becoming obese and to develop obesity-associated diseases.

Tremendous progress has been made recently in understanding the biologic basis of obesity, and I will cite just a few examples. We now understand better how appetite is controlled through newly discovered hormones such as ghrelin and PYY. They are produced by the stomach and small intestine, and signal the brain, respectively, to increase and decrease appetite. Blood levels of ghrelin peak just before meals, and peaks are significantly higher in obese individuals who have lost weight by dieting, perhaps explaining why sustaining weight loss is so difficult. Bariatric, or gastric bypass, surgery is being increasingly performed in the United States, and part of its effectiveness in achieving sustained weight loss may be explained by the recent finding that ghrelin levels are suppressed by some forms of the surgery. Blocking the action of ghrelin is thus a potentially attractive target for drug development

Similar advances are being made in understanding how the body decides whether and where to metabolize or store fat. Discovery of hormones such as leptin and adiponectin secreted by fat have shown that fat signals to brain, liver, and muscle to regulate fuel metabolism and response to insulin. Such discoveries help explain how obesity leads to insulin resistance and type 2 diabetes, and offer new ways of treating or preventing obesity-associated disorders. Epidemiologic results and clinical studies show that differences in distribution of body fat may also be important in determining which individuals develop obesity-associated disorders.

Progress in behavioral research provided the basis for the lifestyle intervention of our Diabetes Prevention Program (DPP), which revealed that participants who lost 5 to 7 percent or more of their body weight and who performed at least 150 minutes of physical activity per week reduced their risk of developing type 2 diabetes by 58 percent. We are conducting a follow-up DPP Outcomes Study to assess the durability of the DPP interventions in preventing diabetes, and to determine whether the interventions reduce cardiovascular disease. Our Look AHEAD: Action for Health in Diabetes clinical trial is testing the effect of sustained weight loss on prevention of cardiovascular disease in obese individuals who already have type 2 diabetes.

To further sharpen the NIDDK's obesity research efforts, I recently announced creation of a new Office of Obesity Research within the NIDDK that is bringing together expertise in our Division of Diabetes, Endocrinology, and Metabolic Diseases, and our Division of Digestive Diseases and Nutrition, both of which have important input to obesity research. This new group is framing initiatives across a wide range of obesity research areas to address the epidemic of obesity, from the fundamental biologic aspects to the behavioral and environmental. Examples include a study of the life cycle of the fat cell directed at discovery of novel targets for treatment of obesity and associated metabolic disorders. In order to address obesity-associated diseases such as type 2 diabetes, we will expand our Diabetes Genome Anatomy Project to include genetic analysis of all the major organ systems affected by diabetes and its complications . We are helping re-engineer the clinical research enterprise by creating a new Bariatric Surgery Clinical Research Consortium (BSCRSC). The BSCRC will develop a common data collection protocol to accelerate clinical research and progress in understanding the development of severe obesity and its complications, as well as understanding the risks and benefits of bariatric surgery as a treatment method.

In behavioral research, we have begun a clinical trial to develop effective strategies to prevent type 2 diabetes in children. This initiative focuses on school-based primary prevention programs to decrease risk factors for type 2 diabetes and lower the incidence of the disorder. We are supporting research to translate the results of the highly successful Diabetes Prevention Program, into clinical practice for prevention of type 2 diabetes in individuals and communities at risk. Of particular interest will be interventions that focus on underserved and minority populations disproportionately affected by the disease. Given the environmental influences fueling the obesity epidemic, we are encouraging research to study promising interventions that would target environmental factors contributing to inappropriate weight gain

in children, adolescents and adults. We are asking investigators to partner with community organizations or businesses, such as schools, supermarkets, restaurants, churches, community groups, and worksites to develop interventions that could potentially be translated into larger-scale interventions.

These are just some of the ways we are encouraging research to combat obesity and its co-morbid conditions. We believe NIDDK and NIH research is our best hope for stemming the tide of this epidemic. Why? Because we stand poised, given new information about the human genome and the advent of new research tools to determine the biologic and genetic factors that make one person more (or less) susceptible to obesity than another. Why is this important? Because it should allow targeted obesity prevention and allow the development of new kinds of drugs and therapies that should be more successful in preventing weight gain and in helping people lose weight and to sustain weight loss. Tied to this is improved research-based behavioral approaches to weight loss and maintenance. In addition, NIH research ultimately will provide the scientific basis for policy decisions on needed changes in environmental factors that affect diet, nutrition, and physical activity. Obesity is a complex problem requiring a multi-disciplinary research approach if we are to reverse this ominous threat to our nation's health.

DIABETES

Approximately one million Americans suffer from a type of diabetes that is not obesity-related. Rather, type 1 diabetes involves immune destruction of the insulin-producing beta cells of the pancreas. We are vigorously pursuing cutting-edge research opportunities for prevention of type 1 diabetes through our TrialNet, and for treatment and cure of type 1 diabetes through support of the field of regenerative medicine. One example of the latter is our Beta Cell Biology Consortium, which brings together multi-disciplinary teams of investigators with expertise in pancreatic development, beta cell biology, stem cell biology, and bioinformatics. Through such collaborative research programs, we are laying a solid foundation for the future development of innovative, cell and regenerative growth factor therapies for diabetes and other debilitating diseases. Increased understanding of beta cell biology should also improve our ability to develop noninvasive, functional imaging technology that would, for example, help monitor type 1 diabetes prevention trials.

HEPATITIS C

The hepatitis C virus is the cause of the most common form of end-stage liver disease in the United States. We recently held a Consensus Development Conference on the management of hepatitis C that recommended directions for future research, and led to development of initiatives that are encouraging further basic and clinical research on hepatitis C, research on management of hepatitis C in people with chronic kidney disease, and research on new therapies for children with hepatitis C. From such research should emerge more effective forms of treatment and prevention.

GASTROINTESTINAL DISEASES

We are bolstering our research activities across the full spectrum of gastrointestinal (GI) diseases, ranging from celiac disease, in which a known dietary factor triggers intestinal damage in genetically susceptible individuals, to functional GI disorders such as irritable bowel syndrome. Our strong research portfolio in inflammatory bowel disease (IBD) is paying dividends. A recent clinical trial reported that a recombinant monoclonal antibody that blocked the action of certain cell adhesion molecules could be used to reduce the symptoms and improve quality of life of patients with Crohn's disease, an inflammatory bowel disease. The NIDDK supported the basic research underpinning this exciting work, providing another example of the critical role of NIH research in the development of therapies for human disease. Our IBD Genetics Research Consortium aims to identify genes associated with increased risk of developing Crohn's disease and ulcerative colitis. The long-term goal is to increase molecular understanding of IBD so as to facilitate development of novel therapies and new diagnostic methods.

KIDNEY DISEASE

We are addressing the sharp rise in end-stage renal disease (ESRD) by supporting research on the causes, treatment, and prevention of the major forms of kidney disease leading to ESRD. The discovery that the proteins encoded by the polycystic kidney disease (PKD) genes are localized to cilia (hair-like projections) in kidney tubular cells demonstrates the rapid progress in understanding the pathogenesis of the

major cause of inherited ESRD. Results from some of our major kidney disease trials have significant implications for clinical practice. Our African American Study of Kidney Disease and Hypertension (AASK) showed that angiotenson-converting enzyme inhibitors, compared with calcium channel blockers, slowed kidney disease progression by 36 percent, and drastically reduced the risk of ESRD by 48 percent in patients who had at least one gram of protein in the urine, a sign of kidney failure.

The Institute's HEMO clinical trial recently showed that the standard recommended hemodialysis dosage and filters are adequate for reducing morbidity and mortality in ESRD patients, and that increasing dialysis dose using a conventional three times per week regimen does not provide greater benefit to patients. However, the important question now is the duration and frequency of dialysis. We therefore have planned clinical trials to compare conventional dialysis with more frequent dialysis in patients with ESRD. We also have launched a prospective epidemiological study of children with chronic kidney disease to determine the risk factors for decline in kidney function, and associated morbidities such as impaired neurocognitive development, cardiovascular disease, and growth failure.

UROLOGIC DISEASES

Our major clinical trial on Medical Therapy of Prostate Symptoms (MTOPS) recently demonstrated that two drugs commonly used to treat benign prostatic hyperplasia (BPH), finasteride and doxasozin, are significantly more effective at preventing symptomatic BPH incidence and progression when given in combination. Samples collected during the MTOPS trial will be used by our new MTOPS Prostate Samples Analysis Consortium to discover and validate biologic markers for detection and risk assessment of BPH.

Our Bladder Progress Review Group report provides a strategic plan for future bladder research. We are already implementing the report's recommendations on interstitial cystitis (IC), a debilitating, chronic syndrome of urinary urgency, frequency, and pelvic pain, by encouraging basic research pertinent to IC, the ultimate goal being the development of reliable diagnostic tools, and new and effective disease treatments and prevention.

Mr. Chairman and Members of the Committee, these are just a few examples of our many research advances and initiatives. I would be pleased to answer any questions.

PREPARED STATEMENT OF DR. STEPHEN E. STRAUS

I am pleased to present the President's fiscal year 2004 budget request for the National Center for Complementary and Alternative Medicine (NCCAM). The fiscal year 2004 budget includes $116,202 million, an increase of $2.9 million over the fiscal year 2003 enacted level of $113,302 million comparable for transfers proposed in the President's request.

INTRODUCTION

Arthritis, depression, menopause, cancer . . . for millions of Americans, these and other health concerns are not being adequately addressed through conventional medicine. Many are turning outside the medical mainstream to approaches that embrace the whole person—mind, body, and spirit. From acupuncture to dietary supplements, complementary and alternative medicine (CAM) approaches are affordable and accessible, but largely untested. Under NCCAM's leadership, researchers are applying the tools of modern science to discover which CAM practices work, why and how they work, and whether they are truly safe. Exploring CAM through rigorous science will lead to the integration of proven CAM practices with conventional medicine, thus improving the lives of all Americans.

STANDARDIZATION & CHARACTERIZATION OF DIETARY SUPPLEMENTS

Dietary supplements, one of the most popular categories of CAM practices, are used by 10 percent of American adults.[1] Many consumers use dietary supplements with the expectation that they are effective in the self-treatment and prevention of disease and the promotion of wellness and, further, with the assumption that they

[1] Hanyu NI, Catherine Simile and Ann M. Hardy, "Utilization of Complementary and Alternative Medicine by United States Adults: Results From the 1999 National Health Interview Survey," Medical Care, Vol. 40, No. 4, pp. 353–358.

are safe. Under the law, supplements are classified as foods and not held to the same rigorous standards as drugs.

Research supported by NCCAM indicates that Americans who take ginseng on a regular basis cannot rely on the label to accurately reflect the product's contents. After examining 25 commercial ginseng products, one NCCAM grantee recently reported that, the concentrations of ginseng differed by as much as ten-fold from the label. The lack of standardized dietary supplements is not only an issue of consumer safety; it is also an issue for researchers who need to protect their patients and work withwell-characterized and standardized products to scientifically and accurately examine study their purported benefits.

NCCAM's recent experience with PC SPES, a patented mixture of eight herbs, is an example of the other vexinganother problem with some dietary supplements contamination. In 2001, thousands of men with advanced prostate cancer in America tookwere taking PC SPES. Based on encouraging early clinical results, NCCAM was supporting four research studies, including a clinical trial, to determine the safety, efficacy, and mechanism of action (i.e., how it works) of PC SPES. In February 2002, the California Department of Health Services and the Food and Drug Administration reported that PC SPES was contaminated with undeclared prescription drug ingredients. This finding led the manufacturer to recall the product and subsequently cease its operations. NCCAM immediately put its studies on hold and convened meetings with scientists, prostate cancer specialists, patients, and industry representatives to determine howif a "cleaner" an uncontaminated product could be made available to the publicreenter the marketplace and the research pipeline, allowing the research to resume. As part of this strategya result of these meetings, NCCAM resumed its laboratory studies of the cellular and molecular biology of PC-SPES and pronounced declared its interest in resuming clinical trials once an unadulterated, fully characterized, and standardized product is available.

NCCAM is taking several steps is taking several stepsto address the critical issue of product standardization and quality. Among the top-selling products in the dietary supplement industry are products like echinacea (*Echinacea purpurea*), taken to prevent and treat colds, milk thistle (*Silybum marianum*), taken to treat chronic hepatitis and cirrhosis, and feverfew (*Tanacetum parthenium*), taken to lower fevers. All of these products have shown promise in small uncontrolled studies; however, each has problems with standardization, precluding their full and objective study. NCCAM is making awards under using the Small Business Innovative Research (SBIR) program to obtain well-characterized and standardized clinical-trial-grade materials of these supplements. This investment in high-quality productsessential first step will be followed by studies to define the optimal dose of each product. To implement this second step, in 2004, NCCAM plans toplans to establish a Dietary Supplement Standardization and Characterization Center (DSSCC), which willto serve as a resource for the analysis of dietary supplements, especially botanical products, before they are used in clinical trials.

DETERMINING THE MECHANISMS OF ACTION OF CAM INTERVENTIONS

While pursuing innovative approaches to ensuring the safety of its clinical trial products, NCCAM continues to support basic and clinical studies NCCAM continues to support basic and clinical studies. The central objective of many of these studies is to examine the mechanisms of action underlying various CAM therapies. In 2002, for example, NCCAM-supported researchers conducted an important body of research on alternatives to conventional hormone therapy—an area of obvious interest for millions of menopausalwomen who are seeking safe and effective alternatives to conventional hormone therapy for relief of menopausal symptoms and related conditions. Specifically, scientists are using *in vitro* systems to examine how some popular dietary supplements act on biochemical pathways responsive to estrogen. Others are examining the estrogenic activity and specific mechanisms of estrogen receptor regulation of a Chinese herbal extract; identifying the active compounds of black cohosh (*Cimifuga racemosa*) and red clover (Trifolium pratense); and investigating the range and mechanisms of action of two plant-based estrogens, genistein and diadzein, and extracts of soy on immune function. These studies will clarify what biochemical effects supplements might have on women and indicate which, if any, are worthy of testing in a clinical trial.

Building on the results of a detailed scientific review that NCCAM conducted with the Agency for Healthcare Research and Quality on the popular dietary supplement, S-Adenosyl-L-Methionine (SAMe), the Center is also supporting mechanistic projects on the mechanisms of action of SAMe that are consistent with the findings of the report associated with key areas identified by the report. One grantee is using cultured cells to better characterize the biochemistry of liver injury and what role

SAMe may play in preventing liver damage. Another investigator is using a mouse model of hepatitis and liver cancer to study the role of SAMe in regulating liver cell growth and death.

A trio of studies indicate that Ginkgo biloba may provide multiple levels of protection to neural tissues and contribute to the body of evidence explaining how Ginkgo may be beneficial in preventing the onset of dementia. NCCAM-supported investigators reported that a standardized Ginkgo extract protects cells from oxidative stress and apoptosis (programmed cell death). Using model systems to study the factors that regulate cell death, the investigators showed that the Ginkgo extracts increase the lifespan of the worm, *Caenorhabditis aenorhabditis elegans, protect cultured neural cells* from undergoing programmed death, and hinder an early step in the biochemical processes leading to neurodegeneration.

In fiscal year 2003, NCCAM made several awards as part of the initiatives it launched with NIH partners to elucidate the underlying biological pathways of the placebo effect and to reveal factors important for eliciting the placebo effect in clinical practice setting. The Center designated mind-body medicine as a priority research area in fiscal year 2003, recognizing the potential contributions to prevention and treatment of chronic diseases that could be made by interventions based on evidence from innovative psychophysiological research. NCCAM will enhance the support for research into the mechanisms of mind-body medicine. Most recently, NCCAM joined other NIH partners to solicit applications from institutions poised to advance research on mind-body interactions and health. The Center also designated mind-body medicine as a priority research area in fiscal year 2003, recognizing the potential contributions to prevention and treatment of chronic diseases that could be made by interventions based on evidence from innovative psychophysiological research.

EVALUATING CAM THERAPIES IN RIGOROUS CLINICAL TRIALS

A chief goal of the basic and preclinical research NCCAM supports isbasic and preclinical research to test therapies for eventual use in clinical trials with the ultimate objective being to translate safe and effective therapies into widespread practice. Another purpose ofIn addition, NCCAM-supported clinical trials is to test CAM products already being widely used by the public. Ultimately, NCCAM wants to answer the central question: "does it work?"

In 2002, NCCAM announced the results of its first large-scale clinical trial. The trial evaluated a one product containing St. John's wort (*Hypericum perforatum*) product, a popular herbal remedy for depression, as a treatment for major depression of moderate severity and found it to be ineffective as compared to placebo. Although the results of this trial were negative showed that St. John's wort is not effective for this type of depression, the outcome provided practitioners and patients alike with valuable data. In addition, the outcome informed researchers who are testing St. John's wort as a treatment for less severe forms of depression. NCCAM is following-up on this finding by co-funding a new trial to test St. John's wort as a treatment for minor depression, a less severe but very common type of depressive illness. The trial begins this year and will enroll 300 patients at three sites nationwide.

Because CAM products and practices are already used by millions of Americans, NCCAM supports relatively morea higher percentage of clinical research than all of the other NIH Institutes and Centers. As part of its clinical research portfolio, the NCCAM extramural research program is already supporting 12 ongoing large-scale clinical trials with other NIH Institutes and Centers. These trials include the largest ever herbalstudy of Ginkgo biloba for the prevention of dementia a critical study given the aforementioned body of evidence that exists regarding Ginkgo's potential protective effects. The list also includes the largest ever studieslargest ever study of dietary supplements (selenium and vitamin E), involving 30,000 men, for the prevention of prostate cancer. In fiscal year 2002, NCCAM cosponsored the first large clinical trial to test chelation therapy as a treatment for coronary artery disease. Also in fiscal year 2002, the NCCAM Intramural Research Program initiated its first clinical trial, which is evaluating electroacupuncture in reducing the severe nausea experienced by many children following intensive cancer chemotherapy. NCCAM is taking actionactive to ensure the quality and safety of NCCAM-supportedits clinical trials.

In 2002, the Center established the Office of Clinical and Regulatory Affairs to help plan, coordinate, and monitor NCCAM-supported clinical trials. All of these activities reflect NCCAM's rich investment in and commitment to clinical research.

BUILDING RESEARCH INFRASTRUCTURE AND INTELLECTUAL CAPITAL

The success of NCCAM's future research endeavors is contingent upon depends on the availability of skilled investigators in both the conventional and CAM research communities. Toward this end, NCCAM is supporting dozens of mentored and independent trainees, from the pre-doctoral level through mid-career and senior faculty members. In 2002, NCCAM made institutional training and clinical research career awards to CAM institutions and joined the new NIH-wide loan repayment program with awards to two junior practitioner-investigators, marking a series of "firsts" for NCCAM.

In addition to its support ofinvestment in training programs, NCCAM continues to support a robust research centers program, providing a critical CAM research infrastructure. In 2002, NCCAM sought to strengthen its centers program by convening sought to strengthen its centers program by cing an expert panel to evaluate the program's current structure and objectives. The panel recommended a more flexible approach to supporting future centers research. This new approach, which employs a mix of funding and research mechanisms, will ideally expand ideally the participation among investigators with varying degrees of research expertise at both CAM and conventional institutions in a multi-disciplinary fashion. Implementation of this strategy began in fiscal year 2003 and will continue through fiscal year 2005.

CONCLUSION

NCCAM has made remarkablesignificant progress in its first 4 years. Between fiscal year 2000 and fiscal year 2001, the number of people enrolled in NCCAM-supported clinical research projects doubled. The Center, in a partnership with other NIH Institutes, launched some of some of the largest clinical studies of CAM therapies ever conducted. NCCAM took pro-activesteps to improve the safety and efficacy of its clinical research studies and the quality of the information disseminated to the public about CAM therapies. Finally, the Center increased its level of support to researchers who are applying cutting-edge scientific tools to study the most promising CAM approaches to the most important public health challenges facing our nation. I look forward to keeping you and the American public apprised of NCCAM's future activities and accomplishments.

PREPARED STATEMENT OF DR. LAWRENCE A. TABAK

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Dental and Craniofacial Research (NIDCR) for fiscal year 2004. The fiscal year 2004 budget includes $382,396,000, an increase of $11,254,000 over the fiscal year 2003 enacted level of $371,142,000 comparable for transfers proposed in the President's Request.

MOLECULAR MEDICINE ENTERS THE MOUTH

When molecular biologists discuss the future of medicine and dentistry, many foresee a day when health care professionals will possess the technological tools to dust a patient's cells, like a detective dusts for fingerprints, and pull up a "molecular fingerprint" of the activity inside. This fingerprint will allow them for the first time to examine the patterns within the cells for disease-causing abnormalities in the genes, proteins, and protein networks. Based on these specific biological clues, doctors will have far more detailed information at hand to make a correct diagnosis and perhaps one day tailor a person's care to treat the specific molecular defects that underlie the disorder.

SALIVARY DIAGNOSTICS

Scientists have long recognized that our saliva serves as a "mirror" of the body's health, in that it contains the full repertoire of proteins, hormones, antibodies, and other molecular analytes that are frequently measured in standard blood tests. The Institute recently launched a major research effort that, in keeping with the National Institutes of Health (NIH) Roadmap initiative, seeks to identify and address major cross-cutting biomedical challenges, and will further develop needed technologies and create the first comprehensive baseline catalogue of all proteins found in oral fluids of healthy individuals. The NIDCR envisions that this basic research could one day translate into miniature, hi-tech tests, or so called "labs" on a silicon chip, that rapidly scan oral fluid for the presence or absence of multiple proteins linked to various systemic diseases and conditions. Ultimately, this approach could

be used for real-time health surveillance—rapidly identifying persons most at risk at the earliest moments of detectable change in key diagnostic markers.

THE GENOMICS AND PROTEOMICS OF PERIODONTAL DISEASES

Although "molecular medicine" is still in its infancy, the NIDCR continues to help lay its basic intellectual foundations. The tools of molecular medicine offer promising new strategies for addressing oral infectious diseases such as periodontitis. These conditions begin when bacteria colonize a "biofilm" that forms on the surface of teeth. Many of these microorganisms remain uncultivated and only recently have some of these bacteria been identified by their molecular fingerprints. Some of these bacteria are highly virulent; they elaborate noxious substances that damage hard and soft tissues of the mouth. Furthermore, oral bacteria can trigger an immune response that often proves destructive both within the mouth and elsewhere in the body. Indeed, recent studies with animal models and epidemiologic surveys have linked periodontal diseases with pre-term delivery and low birth weight.

With the advent of more powerful research tools, NIDCR supported scientists will now be able to assemble a molecular "parts list" of all the genes and proteins involved in periodontal diseases. For the first time, a detailed understanding of the microbial and host signaling pathways that are activated or deactivated during periodontal disease progression will be mapped. This represents an important step in defining new therapeutic targets to overcome one of the most prevalent infectious diseases of humankind.

TISSUE ENGINEERING

The NIDCR continues to invest heavily in regenerative medicine, with a strong interest in engineering new bone to repair dental and craniofacial wounds and birth defects. Of particular interest are adult bone marrow stromal stem cells, the natural progenitors that create the body's bone-forming cells. In recent years, scientists have envisioned healing bone fractures by inserting these cells directly into the wound. The adult stem cells would replicate in the wound, create millions of new bone cells, and heal the fracture rapidly and efficiently. As appealing as this approach is, however, technical challenges have emerged to slow the research. One of the most formidable obstacles is the discovery that adult bone marrow stromal stem cells stop growing soon after they are introduced into cell culture and quickly lose their ability to form new bone. Because hundreds of thousands of stem cells are required to heal even a minor bone fracture, scientists have been hard pressed to generate an adequate supply of these precursors.

For the first time, NIDCR scientists and grantees reported that they have more than doubled the life span of adult bone marrow stromal stem cells, under laboratory conditions, by incorporating the catalytic, or active, component of a much-studied enzyme called telomerase, termed the hTERT gene, into the stem cells. This was particularly interesting because hTERT is the catalytic, or active, component of a much studied enzyme called telomerase. Telomerase has been shown to counter the shortening of telomeres, the tips of chromosomes, by triggering a chemical reaction that adds new base pairs to them and extends the life of the cell. In follow-up animal studies, the scientists found that the newly formed bone, generated from the stem cells, had all of the hallmarks of normal bone—including organized collagen fibers and various mineral components.

SJÖGREN'S SYNDROME

The NIDCR is also applying tissue engineering strategies to Sjögren's syndrome, a relatively rare condition that affects over one million Americans. The syndrome is caused when the immune system mistakenly attacks various parts of the body, often including cells that produce saliva. When this occurs, people develop chronically dry mouths, which can impair their ability to taste and swallow as well as lead to oral disease. While studies are ongoing to pinpoint the root cause of this condition, NIDCR continues to explore the possibility of developing an artificial salivary gland, an approach that one day could help to restore adequate levels of saliva for Sjögren's patients.

In studying Sjögren's syndrome, one of the major barriers always has been logistical. People with the syndrome are scattered throughout the country, and scientists are sometimes uncertain about how to find them. To ensure that researchers have access to sufficient numbers of Sjögren's patients with well defined clinical histories and relevant biological samples, NIDCR will support the first international registry of Sjögren's patients. The registry will be crucial in tracking the incidence and natural history of the condition. It also will allow NIDCR to launch more rapidly the necessary clinical trials to evaluate promising diagnostic and therapeutic

leads as they emerge. NIDCR also plans to identify biomarkers—genes, proteins, or even protein networks—which will allow early diagnosis, determination of disease progression, and stratification of high risk individuals. By developing a battery of sensitive and highly specific diagnostic and prognostic biomarkers, critical molecular information will be available to more accurately diagnose and treat Sjögren's syndrome, a long-held hope of many Americans affected by this condition.

PAIN RESEARCH

For the past four decades, the NIDCR has been one of the key players at NIH in the study of the basic biology and treatment of pain. While current analgesic drugs help many ease discomfort, millions of others have pain management needs that remain completely or partially unmet. Nearly all available analgesics were developed based on overly simplified, linear models of pain transmission. Recent advances show that pain transmission is a far more dynamic process that often involves multiple routes, or pathways. Each pathway integrates a convergence of molecular signals, then relays them along their own specific, hard-wired routes to the brain. The research challenge is to define the molecular details of these multiple routes of pain transmission with the aim of increasing the repertoire of pain management strategies.

In keeping with the NIH Roadmap initiative, progress is now being made in defining the biological pathways and networks of pain. For example, a group of NIDCR grantees have discovered several biological factors that influence pain perception. This multidisciplinary team focuses its research on developing novel, real-time imaging techniques that track the mu-opioid system, a specific type of protein receptor in the brain that researchers have long suspected triggers a dampening of the pain. In a seminal study published last year, the team confirmed the role of the mu-opioid system in enhancing a person's tolerance of pain. According to the research team, this marked the first study ever that combined prolonged pain with simultaneous brain scan monitoring of the mu-opioid system and self-reported pain ratings of human volunteers.

The group found that the onset and slow release of jaw muscle pain (that mimics, in part, the symptoms of individuals suffering from Temporomandibular muscle and joint diseases and conditions) over 20 minutes caused a surge in the release of endorphins, naturally produced chemicals that bind to the mu-opioid protein receptors that are displayed on the surface of brain cells. Once the endorphins activated the receptors, the volunteers said they felt a reduction in pain and emotions related to the sensation. Specific brain regions—especially those that play a role in emotional responses or that help to process signals from the body's sensory systems—had the greatest increase in endorphin levels. The research also revealed major variations among volunteers in baseline and pain-induced levels of opioids. The scientists noted that their results establish that people vary both in their capacity to produce mu-opioid receptors and in their ability to release the anti-pain chemicals themselves. This variability appears to determine the emotional and sensory aspects of a painful experience and might explain why some people react to pain differently. It may also help to explain why some people are more prone to chronic pain conditions or do not benefit from certain anti-pain medications.

The group and its collaborators have published two important followup studies. In the first study, the scientists observed that, at matched levels of pain intensity, men and women differ in the degree and direction of the mu-opioid response in distinct areas of the brain. In particular, men had greater activation of mu receptors in specific regions of the brain—the anterior thalamus, ventral basal ganglia, and amygdala. Women, conversely, had reductions in the resting levels of these receptors when they experienced pain in the nucleus accubens, an area of the brain previously associated with hyperalgesic responses to the blockage of these receptors.

In the second study, the scientists focused on a gene that produces a key enzyme involved in the mu-opiod system. The group found that people who inherit an extremely common variation in the gene have a lower natural threshold of pain than those who were born without the variation. The scientists speculated that the variant gene encodes a slightly altered enzyme that functions somewhat differently than the normal enzyme, leading to lower brain levels of pain-killing endorphins. This finding highlights the growing recognition that pain treatment should be customized to meet the specific needs of individual patients.

Because of the mouth's unique role in the human body, NIDCR is well positioned to make key contributions to the future of molecular-based medicine—not only in alleviating oral conditions but also toward improving systemic health. This Institute's continued contributions represent hope for millions of Americans today, as well as improved health and quality of life for generations to come.

PREPARED STATEMENT OF DR. JUDITH L. VAITUKAITIS

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Center for Research Resources (NCRR) for fiscal year 2004, a sum of $1,053,926, a decrease of $84,738,000 from the fiscal year 2003 enacted level of $1,138,664 comparable for transfers proposed in the President's request.

Infrastructure is at the heart of NCRR. For more than 40 years, it has been NCRR's mission to develop and support essential research resources that strengthen and enhance research environments for health-related studies. NCRR provides the nation's scientific community with access to broad-ranging resources, including animal models, advanced technologies, research facilities, and clinical research centers that explore new approaches for diagnosing, treating, and preventing human disease.

To be responsive to emerging needs, NCRR works in trusted partnership with the biomedical research community, with other NIH institutes and centers, and, in some cases, with other Federal agencies and private sector organizations. In anticipation of emerging needs, NCRR in recent years has funded construction of biocontainment laboratories for the study of dangerous infectious agents; islet cell resources to explore novel therapies for diabetes; and creation of transgenic animals that enhance understanding of human disease.

Scientists today are exploring biomedical problems of enormous complexity. Some of the nation's most pressing health concerns can best be addressed through multidisciplinary research teams, which integrate technologies and expertise from a variety of fields. NCRR, with its cross-cutting mission, is ideally positioned to facilitate this evolving approach. Today I will outline NCRR's plans for meeting the ever-changing infrastructure needs and describe just a few of the research advances enabled through NCRR-supported research infrastructure.

ADVANCED TECHNOLOGIES

NCRR has a long history of developing and enhancing access to new technologies. Magnetic resonance imaging, mass spectrometry, synchrotrons for crystallography and optical imaging are just a few of the now-indispensable tools that NCRR supported in their infancy, primarily through the nationwide network of Biomedical Technology Resource Centers. NCRR must remain positioned to ensure that innovative technologies are developed and accessible before research progress is compromised.

Novel insights into the prevention or treatment of disease will arise from synthesis of massive amounts of molecular, genetic, and biologic data. To take advantage of these rich sources of information, researchers need new bioinformatics tools and approaches to selectively retrieve, analyze, and interpret data stored in many different formats and at different levels of aggregation in locations spread across many sites. Tool development, including new database architecture, is needed to manipulate large data sets with data object entries that vary markedly in size and complexity. Seamless integration of information across these data sources is a major research challenge.

NCRR has begun to address such issues through its Biomedical Informatics Research Network (BIRN). The test bed encompasses diverse locations nationwide. The initial development of BIRN focuses on generating several robust technologies, computational tools, and communications networks. These networks simplify and facilitate the sharing of scientific expertise, technologies, and data. BIRN currently provides links, via Internet2, among several General Clinical Research Centers and Biomedical Technology Resource Centers. NCRR now plans to extend the scope of these networked resources by connecting all NCRR-supported research resource centers to Internet2, which will enhance nationwide access to databases, bioinformatics tools, and enabling resources for clinical and basic research in a second test bed that will concentrate on infrastructure for clinical research.

In another facet of the BIRN development, NCRR will work in concert with other NIH components to expand the advanced technologies used or developed for BIRN and apply them to build a National Electronic Clinical Trials and Research network, called NECTAR. This effort will include designing a web-based approach for entering clinical data, developing advanced tools for integrating datasets, and enabling manipulation of complex datasets from remote sites. Initial development of the NECTAR network will focus on therapeutic development networks, particularly for the treatment of rare diseases. Ultimately, the tools developed for NECTAR may be readily scaled up for larger investigations, including collaboratories.

With today's multifaceted studies, biomedical scientists increasingly depend on a systems approach that integrates, for example, advanced technologies for

macromolecular structures, structure-based drug design, novel technologies to discern the gene-gene interactions and molecular imaging. To enable such studies, NCRR proposes to develop and support comprehensive research resource centers equipped with state-of-the-art technologies and a team of investigators with wide-ranging but complementary expertise. These comprehensive centers, which may provide remote access to resources, will allow investigators to characterize the thousands of proteins expressed by the human genome. Scientists will be positioned to address fundamental questions that cannot be answered by examining one protein at a time. Such "postgenomic" studies may provide clues to complex disease-related processes that may be prevented or arrested with novel interventions.

MODEL DEVELOPMENT AND GENETIC MEDICINE

NCRR is also at the forefront in developing nonhuman models and tools for genetic medicine. In recent years, numerous gene-targeting and transgenic studies have produced a wealth of information on gene function and their role in development, aging, and disease processes. But the enormous volume of collected data is often unwieldy and difficult to analyze. NCRR will enhance this promising area of research by supporting a national network of resources to systematically classify and characterize genetically altered animal models and to support the development of new technologies to rapidly phenotype new mutants. With the decoding of the human genome and development of new technologies, biologic models may help unravel the causes and identify cures for such complex diseases as diabetes, hypertension and cancer.

The mouse has gained new prominence in biomedical laboratories now that scientists can readily modify the animal's genome to create transgenic and "knockout" 1models of human disease. In 1999, NCRR established the Mutant Mouse Regional Resource Centers to expand the nation's capacity for preserving specialized mice and distributing them to biomedical researchers. Because of the program's success and value to the scientific community, NCRR now plans to extend the scope of the mouse resource centers to an international level. Collaborations will be established with Mutant Mouse Resources at sites in Europe and Japan, thereby minimizing unplanned duplicative efforts on a global scale.

NCRR also proposes to initiate a network of Mutant Rat Regional Resource Centers—similar to the successful mouse network—to import, validate, cryopreserve, and distribute mutant rats to investigators globally. Up to three rat resource centers will be established along with a complementary informatics center to design and maintain a database of relevant data for each mutant rat included in the network, and mantain a dedicated Internet linkage among the Centers to provide investigators access the information on validated mutant rat models within the network's collection and relevant information a centralized web site and database.

Research using swine models has expanded significantly over the past five years, resulting in the need for animal production, appropriate husbandry and care, and genetic technologies related to pigs. In 2002, an NCRR-supported research team at the University of Missouri succeeded in creating the world's first "knockout" pigs—the gene function is altered so that the gene can no longer add specific sugars to the outer surface of liver cells, which, in turn, decreases the immune-mediated tissue rejection response. The knockout pigs represented a first step toward developing genetically engineered swine suitable for cross-species transplantation, or xenotransplantation, into humans. NCRR proposes to establish a National Swine Regional Resource Center with the capacity to import, cryopreserve, characterize, maintain, and distribute well-characterized specific-pathogen-free swine strains. The Resource Center will also have an R&D component to enhance the research scope and expertise of investigators there.

PREVENTION, DIAGNOSIS, AND TREATMENT

NCRR is also an ardent supporter of clinical research. The nationwide network of General Clinical Research Centers (GCRCs) provides a collection of research resources and professional research staffing for conducting state-of-the-art clinical research and career development programs to develop independent investigators. GCRCs are encouraged to reach out to investigators at nearby institutions without GCRCs and provide access to the resources of the GCRCs. NCRR also funds clinical research centers at minority institutions.

To address the public's concern about the safety of clinical research, NCRR implemented the Research Subject Advocate (RSA) program to assure that research conducted on NCRR-supported GCRCs and minority clinical research sites are in compliance with Federal laws, regulations and policies. Research Subject Advocates work closely with research subjects to help them understand the research project

for which they agreed to participate and also work closely with clinical investigators to apprise them of their ethical responsibilities to research subjects. The RSA organizes workshops to inform investigators about the several local and Federal regulations and policies that relate to clinical research. Because of the enthusiastic institutional responses to the Research Subject Advocate program, NCRR proposes to begin phasing in support for RSAs for all NIH-supported patient-oriented research at GCRC host institutions.

In addition, NCRR intends to support research to identify factors—for example, biologic, economic or cultural—which lead to health disparities and how to modulate for eliminate those factors in racial and ethnic minority Americans. Through establishing dedicated Comprehensive Centers for Health Disparities Research, NCRR support will develop the clinical research skills and translational research capacity of students, postdoctoral research fellows and faculty at minority medical schools. NCRR also will continue to encourage multidisciplinary collaborations among minority institutions and institutions with established research programs to not only accelerate the development of independent clinical research investigators but also to enhance our understanding of the factors that contribute to health disparities and how to negate them.

ENHANCEMENT OF RESEARCH CAPACITY

NCRR's purview is research infrastructure, in the broadest interpretation of the term. Insight leading to novel research approaches to prevent, treat or ameliorate disease will result from synthesis of massive amounts of molecular, genetic, and biologic data. Seamless integration of information across these data sources is a major research challenge.

NCRR will expand the advanced technology used or developed for the neuroscience testbed for BIRN to build a National Electronic Clinical Trials and Research (NECTAR) network. This effort will include designing a web based data entry approach for clinical trials and other types of clinical research, development of a host of other tools, including advanced grid technology to integrate datasets and develop tools to manipulate these datasets at distributed sites. The NECTAR network will generate heterogeneous data types which have distinct or unique requirements for data collection, storage, integration, and analysis. Initially this phase of the NECTAR network development will focus on therapeutic development networks, particularly in rare diseases. The tools developed at this stage may be readily scaled up to include, for example, collaborative clinical research across wide geographic sites, primary care physician clinical trial networks, other provider networks, and private sector partners. This infrastructure will constitute the foundation for a nation wide NECTAR–BIRN to accelerate the rate for which health research advances at the bench reach patients who are the intended benefactors of biomedical research.

The BIRN allows access to databases, bioinformatics tools, scalable computing up to the teraflop level, research resources for clinical, animal and basic research; it also includes federated databases, web-based data collection for clinical trials and access to virtual laboratories for crystallography, magnetic resonance imaging, electron microscopy. This cyberspace-based network will be intertwined with a "ground-based" network of technology-based resources. The complementary networks will continue to evolve with technologic needs and research complexities. Similarly, technologies and resources networked for human, animal and basic research will also evolve across this national infrastructure for land-based and cyber-spaced networks. In essence, as research problems become more complex, infrastructure to facilitate that research must undergo a paradigm shift.

The Institutional Development Award (IDeA) program includes two subprograms to strengthen the research infrastructure among 23 states and Puerto Rico to improve their research competitiveness for NIH grant awards. The two infrastructure-building programs—Centers of Biomedical Research Excellence (COBRE) and the Biomedical Research Infrastructure Network (BRIN)—have been in place for three and two years, respectively. In that short time span, preliminary observations are extremely encouraging. Between 1997 and 2002, the application rate for NIH grants increased 16 percent—but the number of competitive NIH grant awards increased 37 percent. The IDeA programs' impact has resulted from providing support for modern laboratories and research equipment, recruitment established investigators to lead the research effort as well as to mentor graduate students and junior faculty to become independent investigators. There has been a spinoff to small industry as well. For example, a faculty member of the COBRE in West Virginia has invented a microfludics chip ("lab on a chip") that will enable researchers to analyze and identify proteins more rapidly, an innovation that may lead to new diagnostic strategies and treatments. Both the COBRE and BRIN programs are enthusiastically

embraced by students, mentor-faculty, and institutional leadership. In fiscal year 2004 the NCRR will develop new COBRE research centers and will develop a follow-on program to the BRIN, initially funded as a planning grant, to capitalize on statewide networks to facilitate biomedical research efforts at undergraduate institutions and to further enhance the pipeline for promising baccalaureate and graduate students in fields relevant to biomedical research.

Finally, NCRR will further strengthen institutional biomedical research infrastructure and also design specific programs to develop the research skills of graduate students and junior faculty in both basic and clinical sciences at RCMI and IDeA institutions. Programs will be designed to enhance early career scientists to transition from a mentored research environment to an independent research career to bolster the collective research capacities of this subset of institutions. To continue to address the shrinking pool of clinical investigators, NCRR plans to expand and extend the successful Institutional Mentored Clinical Research Scholars (CRS) Program to include a consortium of minority medical schools associated with the Research Centers in Minority Institutions (RCMI) program. This cohort of investigators will be included in a dedicated network to foster their research through the Clinical Research Infrastructure initiative.

CONCLUSION

In conclusion, the health-related advances of tomorrow will depend on the availability of essential, shared research resources, including nonhuman models, advanced technologies, and tools for exploring new diagnostics, therapies, and preventive strategies. NCRR is poised to provide these essential resources to the biomedical community. As we have for more than 40 years, NCRR remains committed to providing the enabling tools and technologies that advance biomedical science and improve the health of our nation's citizens. In collaboration with the National Science Foundation, Internet2, and investigators from several universities, NCRR has become a major supporter for upgrading the infrastructure for health-related research focusing on development of a bioinformatics tool box, a more efficient clinical trials system and use Internet2 interface for the several tools and algorithms for data visualization, efficient clinical trials networks and development of grids for security, computation, and data storage.

My colleagues and I will be happy to respond to any questions you may have.

PREPARED STATEMENT OF DR. JACK WHITESCARVER

Mr. Chairman and Members of the Committee, I am pleased to present the President's budget request for the AIDS research programs of the NIH for fiscal year 2004, a sum of $2,869,858,000 an increase of $122,395,000 above the comparable fiscal year 2003 appropriation.

The NIH represents the largest and most significant public investment in AIDS research in the world. It supports a comprehensive program of basic, clinical, and behavioral research on HIV infection and its associated opportunistic infections and malignancies that will lead to a better understanding of the basic biology of HIV, the development of effective therapies to treat it, and the design of better interventions to prevent new infections. Perhaps no other disease so thoroughly transcends every area of clinical medicine and scientific investigation, crossing the boundaries of the NIH institutes. The Office of AIDS Research (OAR) plays a unique role at the NIH. OAR coordinates the scientific, budgetary, and policy elements of the NIH AIDS program, supported by nearly every Institute and Center; prepares an annual comprehensive trans-NIH plan and budget for all NIH-sponsored AIDS research; facilitates NIH involvement in international AIDS research activities; and identifies and facilitates scientific programs for multi-institute participation in priority areas of research.

THE WORLDWIDE PANDEMIC

HIV has already infected more than 60 million people around the world. According to a new CIA report, "The HIV/AIDS pandemic continues to spread around the world at an alarming rate, and the number of people with the disease will grow significantly by the end of the decade, as it becomes more geographically diffuse. By 2010, we estimate that five countries of strategic importance to the United States—Nigeria, Ethiopia, Russia, India, and China—collectively will have the largest number of HIV/AIDS cases on earth." A recent article in *Foreign Affairs* magazine stated, "The spread of HIV/AIDS through Eurasia, in short, will assuredly qualify as a humanitarian tragedy—but it will be much more than that. The pandemic there

stands to affect, and alter, the economic potential—and by extension, the military power—of the region's major states . . . Over the decades ahead, in other words, HIV/AIDS is set to be a factor in the very balance of power within Eurasia—and thus in the relationship between Eurasian states and the rest of the world." Dramatic increases in HIV infection also are occurring in Eastern Europe, Central Asia, Latin America, and the Caribbean. An article in the *New York Times* recently reported another dimension to the epidemic: "As a result of HIV, the worst-hit African countries have undergone a social breakdown that is now reaching a new level: African societies' capacity to resist famine is fast eroding. Hunger and disease have begun reinforcing each other."

THE U.S. EPIDEMIC

The Centers for Disease Control and Prevention (CDC) recently reported that more people were diagnosed with AIDS in 2001, the latest year for which reliable statistics are available, than the previous year, or any year since 1998. After years of sharp declines, thanks largely to successful treatment with new antiretroviral therapies (ART), this report indicates a reversal in cases of AIDS in the U.S. Further, CDC reported that the rate of new HIV diagnoses, which had remained stable since 1990, also appears to be increasing. New HIV infections rose a striking 8 percent between 1999 and 2001, based on data from 25 states with mandatory HIV reporting, which does not include the two highest prevalence states of New York and California. HIV infection rates continue to climb among women, racial and ethnic minorities, young homosexual men, individuals with addictive disorders, and people over 50 years of age. In addition, use of ART has now been associated with a series of side effects and long-term complications that may have a negative impact on mortality rates. The appearance of multi-drug resistant strains of HIV presents an additional serious public health concern. According to CDC reports, approximately one quarter of the HIV-infected population in the United States also is infected with Hepatitis C virus (HCV). AIDS affects African Americans and Hispanics disproportionately. According to CDC figures through December 2001, approximately 64 percent of newly infected women are African American and 17 percent are Hispanic. Among newly infected men, approximately 43 percent are African American and 20 percent are Hispanic. This expanding and evolving U.S. epidemic presents new and complex scientific challenges.

COMPREHENSIVE AIDS RESEARCH PLAN AND BUDGET

To address these compelling scientific questions, the OAR develops an annual comprehensive trans-NIH AIDS research plan and budget, based on the scientific priorities and opportunities that will lead to better therapies and prevention strategies for HIV infection and AIDS. The planning process is inclusive and collaborative, involving the NIH Institutes, as well as eminent non-government experts from academia, industry, foundations, and AIDS community representatives. The Plan serves as the framework for developing the annual AIDS research budget for each Institute and Center, for determining the use of AIDS-designated dollars, and for tracking and monitoring those expenditures.

The Plan establishes the NIH AIDS scientific agenda in the areas of: Natural History and Epidemiology; Etiology and Pathogenesis; Therapeutics; Vaccines; and Behavioral and Social Science. In addition, the plan addresses the cross-cutting areas of: Microbicides; Racial and Ethnic Minorities; Women and Girls; Prevention Science; International Research; Training, Infrastructure, and Capacity Building; and Information Dissemination. In consultation with the Director of NIH, the OAR determines the total annual AIDS research budget. Within that total, the OAR establishes the AIDS research budgets for each NIH Institute and Center, in accordance with the priorities and objectives of the Plan, at each step of the budget development process up to the Conference Committee. To accomplish this, OAR consults regularly with the Institute and Center Directors. This process allows the OAR to ensure that NIH AIDS research funds will be provided to the most compelling scientific opportunities, rather than a distribution based solely on a formula.

OAR plays a crucial role in identifying scientific areas that require focused attention and facilitating multi-Institute activities to address those needs. OAR fosters this research through a number of mechanisms, such as designating funds and supplements to jump-start or pilot program areas, sponsoring workshops or conferences to highlight a particular research topic, and sponsoring reviews or evaluations of research program areas to identify research needs.

The overarching priorities that continue to frame the NIH AIDS research agenda are: prevention research to reduce HIV transmission, including development of vaccines, microbicides, and behavioral interventions; therapeutics research to develop

simpler, less toxic, and cheaper drugs and drug regimens to treat HIV infection and its associated illnesses, malignancies, and other complications; international research, particularly to address the critical needs in developing countries; and research targeting the disproportionate impact of AIDS on minority populations in the United States. All of these efforts require a strong foundation of basic science, the bedrock of our research endeavor.

NEW CHALLENGES IN THERAPEUTICS RESEARCH

While multiple ART drug combinations continue to successfully reduce viral load and restore immune responses in many HIV-infected individuals, these regimens also can result in serious toxicities and side effects, single- and multiple drug-resistance, and other complications which make them unacceptable for some individuals. These side effects and complications appear to be increasing as HIV-infected individuals continue on drug regimens. More deaths occurring from liver failure, kidney disease, and cardiovascular complications are being observed in this patient population. NIH-sponsored research efforts continue to develop better antiretroviral drugs and treatment regimens that demonstrate less toxicity, activity in viral and cellular reservoirs, reduced development of drug resistant virus, improved pharmacodynamics and pharmacokinetics, easier compliance, and lower cost.

While the incidence of certain opportunistic infections (OIs) and malignancies has decreased with the advent of ART, the number of cases of TB, multiple drug resistant TB, and other coinfections such as Hepatitis B virus and Hepatitis C virus has increased. The development of practical and affordable treatment regimens against HIV coinfections and endemic diseases in developed and developing nations is an NIH priority.

PREVENTION RESEARCH

NIH supports a comprehensive approach to HIV prevention research that includes contributions from the biomedical, behavioral, and social sciences. Our biomedical prevention research priorities include the development of vaccines, topical microbicides, strategies to prevent mother-to-child transmission-including a better understanding of risk associated with breast-feeding-and management of sexually transmitted diseases (STDs). NIH also supports behavioral research strategies, including interventions related to drug and alcohol use. Efforts continue to identify the most appropriate intervention strategies for different populations and subepidemics in the United States and around the world. As a result of increased NIH funding, many new approaches to HIV vaccines are being pursued. Although production of candidate vaccines for clinical study has proceeded slowly, at least 10 new candidate vaccines will enter Phase I trials in the next 2 years. Several new combinations of products, which are expected to provide better immune responses, also will be tested in Phase I or II trials. The Dale and Betty Bumpers Vaccine Research Center, located on the NIH campus, recently launched the first Phase I clinical trial of a multi-clade, multi-gene vaccine candidate.

INTERNATIONAL RESEARCH

To address the increasing urgency of the AIDS pandemic, the OAR established an initiative and strategic plan for global research on HIV/AIDS and has significantly increased research efforts in the past several years to benefit resource- and infrastructure-poor nations. NIH supports a growing portfolio of research conducted in collaboration with investigators in developing countries. Results of this research benefit the people in the country where the research is conducted, as well as people affected by HIV/AIDS worldwide. Critical to the success of these international studies are foreign scientists who are full and equal partners in the design and conduct of collaborative studies. To that end, NIH also supports international training programs and initiatives that help build infrastructure and laboratory capacity in developing countries where the research is conducted.

WOMEN AND MINORITIES

Women experience HIV/AIDS differently from men. NIH research has demonstrated that women progress to AIDS at lower viral load levels and higher CD4 counts than men. Women also experience different clinical manifestations and complications of HIV disease. These findings may have implications for care and treatment of HIV-infected women, particularly with ART. There are many research questions that remain unanswered about specific characteristics of women and girls that might play a role in transmission, acquisition, or resistance to HIV infection during different stages of the life course.

In many U.S. urban centers, HIV seroprevalence rates mimic those found in some developing nations. These findings, along with the resurgence of STDs and associated high-risk behaviors, demonstrate the need for comprehensive strategies to decrease HIV transmission in affected vulnerable populations, and improve treatment options and treatment outcomes. OAR is directing increased resources toward research to develop new interventions that will have significant impact on these groups. These include interventions that address the co-occurrence of other STDs, hepatitis, drug abuse, and mental illness; and interventions that consider the role of culture, family, and other social factors in the transmission and prevention of these disorders in minority communities. NIH is making significant investments to improve research infrastructure and training opportunities for minorities and will continue to ensure the participation of minorities in AIDS clinical trials, as well as in natural history, epidemiologic, and prevention studies. OAR has provided additional funds to projects aimed at increasing the number of minority investigators conducting behavioral and clinical research; targeting the links between substance abuse, sexual behaviors, and HIV infection; increasing outreach education programs targeting minority physicians and at-risk populations; and expanding the portfolio of population-based research. One of these projects is a series of Training and Career Development Workshops that provide minority investigators with an opportunity to learn more about available NIH funding mechanisms and to meet and network with senior minority investigators who receive significant levels of NIH funding.

SUMMARY

The human and economic toll of the AIDS pandemic is profound. It requires a unique response that is complex, comprehensive, multi-disciplinary, and global. The NIH role in this response is fundamental and unprecedented. The diverse AIDS research portfolio demands scientific coordination and management of research funds to enhance collaboration, minimize duplication, and ensure that precious research dollars are invested in the highest priority areas of scientific opportunity. The nation's investment in AIDS research is reaping even greater dividends, as AIDS research is unraveling the mysteries surrounding many other infectious, malignant, neurologic, autoimmune, and metabolic diseases.

The authorities of the Office of AIDS Research allow NIH to pursue a united research front against the global AIDS epidemic. We are deeply grateful for the continued support this Committee has provided to our efforts.

ACTING DIRECTORS

Senator SPECTER. Thank you very much, Dr. Zerhouni.

Are there any other institutes which have acting directors at the present time?

Dr. ZERHOUNI. Yes. We have three institutes this minute. NIGMS, the General Medical Science Institute is—the Acting Director is Dr. Judy Greenberg. And she is with us today.

Senator SPECTER. And when do you expect to have a permanent director there?

Dr. ZERHOUNI. Senator, I have worked—the top priority for my first year was to complete all six—I mean, to fill all six vacancies for the six institutes that were vacant within the year. So I expect that, I hope on my first anniversary that all institutes will have new directors that have acting directors today.

Senator SPECTER. Dr. Zerhouni, the subcommittee would appreciate knowing a little more about your efforts there. There is an inevitable sense that a full-time director with that authority is necessary to move an institute along at top speed. So would you submit to us in some detail, in writing, your expectations and the progress and keep us informed as to how you are doing on full-time directors for those institutes?

Dr. ZERHOUNI. I will certainly do. And I agree with your views on that.

[The information follows:]

PROGRESS ON FULL-TIME DIRECTORS

Mr. Chairman, I consider the selection of outstanding, highly qualified scientist-administrators as directors of the various institutes to be among my highest priorities. Over the past eleven months, I have filled three of the vacancies for Directors of Institutes at NIH and have appointed:

Dr. Thomas Insel, Director, National Institute of Mental Health

Dr. T. K. Li, Director, National Institute on Alcohol Abuse and Alcoholism

Dr. Nora Volkow, Director, National Institute and Drug Abuse

Two other vacancies remain and I and my staff are working very hard to complete the searches so that I can make appointments:

—The search for the Director, National Institute of Neurological Disorders and Stroke has been prolonged, unfortunately. It started in March, 2001 and, after careful consideration, the leading candidate withdrew and took a position at a pharmaceutical company in November, 2001. The vacancy announcement was re-issued and a slate of three highly qualified candidates was sent forward, all of whom were interviewed by the Acting Director, NIH between late February and March, 2002. A candidate was offered the position at the end of March, accepted verbally and subsequently, withdrew in early April 2002.

Upon my assuming the Directorship of NIH, I discussed the situation with my senior staff and decided to reconstitute the search committee, and solicit applicants myself. This resulted in several new applicants and consideration of several previous candidates. Five candidates were interviewed and as of the time of submission of this response, I am in active discussion with my selectee. I anticipate that I will be able to name a Director for NINDS within a very short time.

—The search for the Director, National Institutes of General Medical Sciences was initiated in mid-March, 2002. The search committee interviewed a total of ten candidates between late September, 2002 and February, 2003. Of the group, I and my senior staff have interviewed three during March and early April and anticipate conducting one more interview. I anticipate that a selection will be made in the next month.

SALIVARY DIAGNOSTICS

Senator SPECTER. Dr. Zerhouni, one of the questions which we characteristically ask is the question about what progress is being made on major ailments and what could be done with greater funding. And it is obviously a very difficult question. It may be an impossible question when we ask when will a cure be found for Parkinson's. I choose Parkinson's because 5 years ago there were estimates that Parkinson's would be cured within 5 years.

Nobody can hold you to a cure time. But we would be interested in your projection on where you see NIH heading on the ailments to give us some projection as to what your expectations are. We understand that it is not possible to be scientifically precise. And then to tell us what more you can do with increased funding, what level of funding on the specific ailments would enable you to project an earlier time and by how much.

Our colleagues in the Congress are very goal-oriented. And even questions which are really not answerable with precision are pursued. So to the extent that you could give us some ideas on those questions, the subcommittee would be very appreciative.

Let me turn to Dr. Lawrence Tabak of the Dental Institute on a question which has recently come to the attention of the subcommittee on the presence of a cancer-related protein in saliva that could result in more acute, less costly ways to diagnose breast cancer in women. The question, Dr. Tabak, is, how much is being requested in the budget to pursue this line of research? And do you have any plans to conduct clinical trials in this area?

Dr. TABAK. Thank you for the question, Senator Specter. In this current fiscal year, NIDCR is expending approximately $7 million

in the general area of salivary diagnostics. And for the next fiscal year, we hope to spend approximately $1.5 million more to continue in this effort.

Senator SPECTER. $1.5 million?

Dr. TABAK. Yes, sir, that is correct.

Senator SPECTER. What is the total budget of your institute?

Dr. TABAK. Currently, it is $371 million, sir.

Senator SPECTER. Does this new test pose real promise to give an easier, better diagnosis of breast cancer?

Dr. TABAK. This and other salivary diagnostic tests do offer a great deal of promise, sir. The test to which you are referring, as you know, was worked out at the University of Mississippi. It is a test which recognizes a protein which can be found both in blood and saliva. But because of the ease of detection and the ease of sample collection in saliva, we feel that there are certain advantages for the saliva-based test.

Senator SPECTER. Dr. Tabak, if you allocated more than $1.5 million, do you think you could get a faster result on this important test?

Dr. TABAK. Certainly, sir, resources are always welcome. But there is a point at which basic information needs to be gathered. And until that basic information is obtained, it would be premature to expend additional funds in a particular area.

Senator SPECTER. Are you saying that is the maximum amount that can be efficiently spent on that research?

Dr. TABAK. In terms of bringing this work to a full-blown clinical trial, sir, I think it would be premature. What we are now doing is termed phase-one trials to begin to understand whether or not this test is both accurate and efficacious. Once that base information is obtained, sir, then it would be appropriate to go on to larger scale trials.

Senator SPECTER. Thank you.

Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman.

PEDIATRIC RESEARCH

Dr. Zerhouni, when you were confirmed, you and I talked about pediatric research. And I wanted to ask you today about any progress you have made. I think we have made a lot of progress on reducing gender bias, but I am still deeply concerned that we have not made much progress on making sure that we are looking at everything in terms of what happens to children.

Can you give us an update on your pediatric research initiative?

Dr. ZERHOUNI. Well, as you know, the pediatric research initiative is guided by a major document that we have been following in terms of implementation. There is no doubt in my mind that pediatric research is a priority, continues to be a priority. We have to also invest and continue to invest in the multiple areas of pediatric research.

We are, for example, invested in terms of talent and developing talent and training capabilities for pediatric research. We are continuing to make investments in many of the pediatric diseases separately. For example, we have increased our investment in mus-

cular dystrophy or increased our investment in spinal muscular atrophy. And in every category we have a disease-specific plan.

But in terms of the overall investments in pediatric research, we need to integrate the pediatric research agenda within not just the NICHD Institute, which is primarily responsible for pediatric research, but all institutes.

So I think it is work in progress. I think we are making good progress. But we will continue to consider that a priority, realizing as well, Senator, that many of the changes we need to make relate to these priority areas that I described—multidisciplinary teams that should invest in pediatric research, clinical research networks. For example, the Office of Rare Diseases is looking at establishing networks across the country to look at these rare diseases that tend to affect children.

So we are looking at a multi-pronged approach and a strategic approach in pediatric research.

FUNDING OF RESEARCH PRIORITIES

Senator MURRAY. Dr. Zerhouni, as you well know, there is a lot of misunderstanding about NIH research dollars. There is kind of this assumption out there that NIH only funds politically correct diseases or that you have to have a high-profile celebrity in order to secure any NIH funding. And I know this subcommittee under Senators Specter and Harkin have really resisted any efforts to earmark NIH dollars by disease. We can express our thoughts through report language.

But could you explain for us how you establish the priorities for NIH funding and what criteria is used in evaluating research applications?

Dr. ZERHOUNI. Certainly, Senator. This is a question that is a recurring theme, especially when any particular area feels underserved. So that when we look at the decisionmaking process, we realize that there are fundamentally several factors that come into play. One, the first and foremost is the burden of the disease as we know it through epidemiological studies. And second, the predicted future burden of disease.

For example, just as a matter of example, you look at diabetes and the rise in expenditures in diabetes, it parallels what we predict the burden of disease in diabetes is going to be. When you look at obesity research, we are now investing at an accelerated pace in obesity research because of the prediction. Even though when you look at the disease burden, per se, you cannot really decide that this is the only factor that you should look at, because the second factor is, have we made enough scientific advances to invest in the particular area with results that are likely to occur?

So we look fundamentally at the investments in terms of, A, the burden of disease; B, the priority setting in terms of science. And we get advice in that context for many more sources than any. I am very impressed with the fact that NIH receives advice from 21,000 advisors every year on every single condition that we face.

So the process is not an easy one to consider. But clearly, the patient advocacy groups are also interested in looking at how we invest. And my gratitude goes to you, because I think earmarking would not be a good direction for setting scientific priorities at

NIH. And we try to avoid that and try to not be politically correct, as you state.

Senator MURRAY. Well, I think it is really important to keep talking about how you set your criteria to the general public, because we do have a misperception constantly that if you get a high-profile person, that you get more funding. And so it makes it harder on us. And, as I said, Senator Specter has done a really good job managing that. But it is very difficult.

I think it is important that we base it on science. So I appreciate your comments.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Murray.

Dr. Zerhouni, I broach the subject of some delicacy now, which has already been communicated to you. Last year the Senate figure was cut by $25 million because the conference committee concluded that to reach the doubling, which was an astronomical figure, was more than sufficient. We have an enormous number of complaints from other research agencies about, candidly, the favoritism that NIH gets. And we have fought those battles out.

We have heard from a number of people about directors of the institutes who have said that certain grants could not be applied or certain research could not be undertaken because the budget was cut and have attributed the $25 million reduction, which was not a cut at all, because there was an increase of more than $3.7 billion to the NIH budget.

It would be amazing, I think, to many of you ladies and gentlemen, how fast the information travels from what you may tell someone who is applying for a grant or you may tell someone who is concerned about more research right back to my ears. You would be surprised.

The advent of this very, very heavy increase in funding for NIH, which has come from this subcommittee, has had the reverberating effect of having this subcommittee contacted by many, many, many people, which had not been the case before we took up the cause of increasing the NIH grant. So if you do not want to make some allocation or you do not want to make a grant or you do not want to undertake some research, if you say it is because you got a cut in your budget, that is going to come back to the Congress.

We hope you do not ever have a cut in your budget. But bear in mind that these people—and I know you have a good sense of this yourself—feel so very intently about these subjects, very, very emotional, when you have a child with one of these maladies, it is just the edge of the ledge. And I know that you dedicated men and women are well aware of that. But I thought it important to make a quasi-public statement. I have not said very much on the subject in the brief remarks I have just made.

Let me turn now to the question of stem cell research. And I would like to direct this question to Dr. James Battey of the Deafness Institute and also to Dr. Allen Spiegel of the Diabetes and Digestive and Kidney Institute. Last September, this subcommittee held a hearing regarding the implementation of the Federal stem cell policy. And as you all know, back on August 9, 2001, President Bush articulated a modification of Federal policy to allow Federal funding on existing stem cell lines.

At the September 25, 2002 hearing, Dr. Curt Civin stated, "Embryonic stem cell research is crawling like a caterpillar, while NIH has listed eligible lines in its registry at 78. Only a tiny fraction of these lines are accessible and only to those persistent and patient enough to jump through a series of hoops and endure lengthy waits. I am still waiting to receive my first stem cell line."

Dr. Battey and then Dr. Spiegel, what steps has NIH taken to help people like Dr. Civin and other scientists gain access to embryonic stem cell lines? And how many are now accessible?

ACCESS TO EMBRYONIC STEM CELL LINES

Dr. BATTEY. The process of scaling up an embryonic stem cell derivation to the point where it can be distributed as a high-quality, well-characterized cell line takes about a year from start to finish. It is an expensive, time-consuming, technically demanding process that requires enormous care to maintain the cells in their state of pluripotency, which means their ability to differentiate into many different cell types, as well as to remain continuously self-renewing.

To facilitate this very expensive and time-consuming process, the NIH has awarded infrastructure grants awards to eight suppliers that have derivations on the NIH stem cell registry. And I am pleased to tell you, Mr. Senator, that between the September hearing and the hearing today, if you had a research laboratory and wanted to order cell lines, in September you could have ordered five such cell lines. And right now, you could order 11 lines today.

That effort is continuing to expand. And we expect that increasing numbers of cell lines will be widely available and actively shipped to the research community over the next 6 months to a year.

Senator SPECTER. How many stem cells are currently available?

Dr. BATTEY. You could order 11 lines today.

Senator SPECTER. Is that sufficient for the research which people want to undertake?

Dr. BATTEY. At this point in time, the fundamental challenge in the human embryonic stem cell research arena is a basic research challenge. It is a challenge to understand what growth factors, transcription factors, and other molecules regulate the ability of embryonic stem cells to differentiate into one cell type versus another. It is an understanding of the interaction between the host and the transplanted cell that allows that cell to persist for a long time within the host and to function correctly.

It is a challenge to understand how you control the cell cycle division of the cell, because once it is transplanted into a host, you do not want it to continue to be self-renewing in the same way that it was in the laboratory before it was transplanted.

These basic research questions are readily addressable with the cell lines that are currently available and will become available within the next few months to a year.

Senator SPECTER. Do we have sufficient stem cell lines for the research that people want to undertake?

Dr. BATTEY. We have sufficient cell lines to embrace the basic research challenge that is in front of us today.

Senator SPECTER. Well, is there some facet besides the "basic research challenge," which is in front of us today?

Dr. BATTEY. The major questions that confront the stem cell research community today can be addressed with the cell lines that are available.

STEM CELL INFRASTRUCTURE AWARDS

Senator SPECTER. Dr. Spiegel, would you care to amplify on Dr. Battey's answer?

Dr. SPIEGEL. I would be happy to. Thank you, Senator Specter.

Some general comments to amplify on what Dr. Battey said would include the provision of support through so-called infrastructure awards to the providers of these human embryonic stem cell lines. NCRR is funding the majority of these infrastructure awards. NIDDK is funding two of them. And this provides support to allow the distribution of these cells because they are very, very difficult to grow.

Several NIH institutes have combined to provide training courses. As Dr. Battey has emphasized, one of the rate-limiting steps here is bringing new investigators into the field. It is not trivial to learn how to grow human embryonic stem cells. And these training courses are directed at that.

A further example, which again comes out of the NIH Stem Cell Task Force, for which Dr. Zerhouni appointed Dr. Battey the Chair and on which I am pleased to serve, is an intramural NIH facility, which will be under Dr. Ron McKay and the Neurology Institute with extramural investigators as advisors. This effort will be comparing and looking critically at the different available human embryonic stem cell lines to provide information that is critical before investigators order them to work on in their own lab.

Let me then just briefly speak on NIDDK specifically. NIDDK, like many of the other NIH institutes, has invested heavily in all aspects of stem cell research. So-called adult stem cell research, animal stem cell research, because animal models are very important, as well as human embryonic stem cell research. The aggregate figure for fiscal year 2002 for NIDDK was $58.3 million.

One particular new initiative that we undertook, based on a trans-NIDDK planning group was so-called stem cell genome anatomy projects. These span the entire spectrum of the NIDDK mission so that we have projects directed at understanding the development of cells in the bone lineage, which we do with the Arthritis Institute, in the gastrointestinal and liver lineage, in the urology and the kidney lineage, and then so-called hematopoietic stem cells.

One of our most important initiatives relating specifically to Type 1 and Type 2 diabetes is the so-called beta cell biology consortium. Of course, it is the beta cell that makes insulin, which is lacking in Type 1 diabetes and deficient in Type 2 diabetes. This consortium is looking at every avenue of approach to the development of these critical cells.

Thank you.

STEM CELLS AND MOUSE FEEDER CELLS

Senator SPECTER. Dr. Spiegel, what about the research to isolate stem cells without the use of mouse feeder cells?

Dr. SPIEGEL. Currently, to my knowledge, although there have been reports from industry about the ability to grow human embryonic stem cells absent mouse feeder cells, the lines that are in use or available that Dr. Battey referred to do use mouse feeder cells. As Dr. Battey emphasized, this is not hampering the ability to do the basic research that we need to do to really be able to understand how we can trigger in a very organized and efficient way the development of these cells into various therapeutic possibilities.

Senator SPECTER. Is it not true that research without the use of mouse feeder cells is indispensable, necessary to use those stem cells in humans?

Dr. SPIEGEL. I totally agree. The comment that I was going to make is that a critical intermediate step before anyone should contemplate—in terms of safety and every other consideration—going into human trials, would be animal models, from small animal models and eventually to non-human primate models. Here, too, the mouse feeder layer issue is not rate-limiting.

But, you are certainly correct that to go into human trials, there would be issues that would have to be addressed in terms of possible mouse viruses and other contaminating proteins.

Senator SPECTER. Should not those issues be addressed now by NIH?

Dr. SPIEGEL. I think that that is an important issue. I think that, in terms of the available lines, there are important technical developments that can be undertaken that are critical to understand what the factors are that these mouse feeder-layers are eliciting that are necessary to keep the human embryonic stem cells from differentiating spontaneously. That is really the critical issue for which they are used.

I believe that the kind of research that is being done, research that we can support, will very much address those kinds of issues. That is, after all, the goal, to really understand how to trigger development along a pathway that we want, and yet to prevent spontaneously differentiation. And such growth factor and other signaling research is being undertaken.

Dr. BATTEY. If I could, Mr. Senator. Dr. Spiegel——

Senator SPECTER. Wait just a minute. I find that very interesting, if not totally understandable. But what about the basic question of having some research without the use of mouse feeder cells? Do you not think that would be a pretty good idea with all you are doing? How many millions did you say you were spending?

Dr. SPIEGEL. The total figure for NIDDK for fiscal year 2002 was $58.3 million.

Senator SPECTER. Well, why not some research without the mouse feeder cells? If they are to be used in humans, you are going to have to move in that direction.

Ladies and gentlemen, what I want to be sure about, and I cannot quite accomplish it in this hearing today, is that we are not making any political decision, that you are making scientific deci-

sions. That is what we expect from you scientists. That is why we are putting up $27 billion, which is a very, very big public trust.

Do you want to say something more, Dr. Battey?

MOUSE FEEDER CELLS

Dr. BATTEY. I just wanted to add to what Dr. Spiegel said. The first challenge to getting rid of the mouse feeder layer is figuring out what the mouse feeder layer is providing to the embryonic stem cells to render them able to differentiate into many different cell types and be self-renewing. And there is active research efforts to identify the factors that allow these cells to remain in that state. And when those factors are known and understood, we will be in a position to attempt to grow these cells absent a mouse feeder layer.

Senator SPECTER. Dr. Penn, let me direct a question to you with respect to spinal muscular atrophy, a genetic motor neuron disease characterized by the wasting away of skeletal muscles. It is the leading killer of infants and toddlers. Twenty-five thousand Americans have the disease with up to 1,000 new babies born with the disorder each year.

While there is a transitional research program, we are concerned about how effectively it is being put into operation. When spinal muscular atrophy was selected for this transitional research program—when was SMA selected for this transitional research program? And when will the first grants be awarded?

Dr. Penn.

SPINAL MUSCULAR ATROPHY RESEARCH

Dr. PENN. Yes, Senator. Spinal muscular atrophy actually is the leading genetic cause of infant mortality. It is not always lethal—there are three or four forms of it. In one form, it is really deadly to babies. But in several others, adults can grow and function and live with this disease.

Spinal muscular atrophy, we feel, is a great scientific opportunity, because we not only know the genetic defect, but we know something about how to try to render this disease perhaps not cured, but to help it by dealing with the genetic defects. And therefore, we did decide to move this disease toward treatments, and I must say with a lot of help from the voluntary agencies, as well as the Muscular Dystrophy Association. And this is actually part of an institute-wide effort to move in what we call translational research, dealing with the basic mechanisms of a disease and then going to treatments.

So we do have a brand-new way of pursuing working toward trying these treatments and doing clinical trials. We will go to the point of an investigational new drug application with FDA. And it has taken time to do this properly. This is so new that we have worked very hard to make it—to have a really excellent product.

Actually what we are going to do is have a contractor issue subcontracts. And the subcontracts will be directed at the group of investigators out there that have done wonders to figure out what is going on with this disease since the gene was identified in 1995.

So we will not be issuing grants. The contractor will actually call for subcontracts. We expect the whole group of investigators to

come in for these. There will then be let a contract. And they will have to achieve milestones. It is not so much reporting on what you—yes, reporting on what you have done. You have to achieve something.

There are drugs, actually drugs, that could be used in this disorder. And one of our intramural investigators, who is internationally recognized in these areas, is trying one of these drugs right now. But he is only working on cell lines from the patients. Again, we have to be very careful about using some of these things and moving to human beings.

It has taken time. But we are issuing—we have issued the requests for proposals for this contract. And we expect to have this move by the end of the summer.

Senator SPECTER. Dr. Penn, the question is, when was SMA selected for this transitional research program?

Dr. PENN. Over a year ago. It took a year and a half to get it to this point.

Senator SPECTER. Well, when will the first grants be awarded?

Dr. PENN. The first subcontracts, sir, will be awarded, I would say, this winter.

Senator SPECTER. When?

Dr. PENN. This winter, sir.

Senator SPECTER. Why is it taking so long?

Dr. PENN. To do it properly and to get our intramural program up and running with it and to make sure that we develop and design this whole program so that we would have a really excellent result.

Senator SPECTER. Well, why does it take almost 2 years, Dr. Penn?

Dr. PENN. As I said, sir, this is something brand-new for us. It is a contract-based program. And it has taken 2 years.

Senator SPECTER. It is something brand-new, but it is a contract-based program.

Dr. PENN. It is brand-new for us. And we have—we are going to have a steering committee made up of the experts, both academic and——

Senator SPECTER. You are going to have a search committee?

Dr. PENN. A steering committee, sir, to run——

Senator SPECTER. You are going to have a steering committee?

Dr. PENN. For it to run——

Senator SPECTER. Has the steering committee been appointed?

Dr. PENN. It is being appointed right now.

Senator SPECTER. Why does that take so long?

Dr. PENN. Well, we had not gotten to that phase of the exercise.

Senator SPECTER. Well, why have you not gotten to that phase?

Dr. PENN. It just took this long to do this properly. It took this long——

Senator SPECTER. Dr. Zerhouni, would you take a look at that and submit in writing——

Dr. ZERHOUNI. Yes, Senator.

Senator SPECTER [continuing]. What has happened?

Dr. ZERHOUNI. I have looked——

Senator SPECTER. I would like to have—but I am not going to take it up now.

Dr. ZERHOUNI. Fine.

Senator SPECTER. I would like to have precise answers as to when the program was adopted, as you call it a translational research program.

Dr. ZERHOUNI. Understood.

Senator SPECTER. And when a steering committee is adopted. And this subcommittee wants to examine whether there is an appropriate sense of urgency. It certainly has not satisfied a lot of parents whose children have this ailment.

Dr. ZERHOUNI. I will respond directly to you on the record, sir.

Senator SPECTER. Okay. We would appreciate it, if you would.

[The information follows:]

SPINAL MUSCULAR ATROPHY

The NIH is committed to accelerating research toward finding a treatment for SMA, and fully appreciates the sense of urgency expressed by the parents of children with this disease, as it does the concerns of the parents of children affected by the scores of other neurological disorders—many of which are genetic and are often disabling or lethal. The NINDS recently launched a comprehensive program designed to encourage and support translational research for all neurological disorders. By translational research, I mean the process of applying insights and discoveries from basic scientific inquiry to the treatment or prevention of disease; the emphasis is on those activities focused on bringing therapeutic strategies to readiness for clinical testing.

The specific, contract-based, SMA translational project to which you refer is in addition to all the other funding opportunities that are currently available for SMA research. It will use a performance-based contract mechanism to allow rapid funding of translational research, in a milestone-driven process, to identify treatments for SMA. The NINDS presented the idea for this program to its National Advisory Neurological Disorders and Stroke Council in February 2002.

The primary contract for the SMA project, which we expect to award on or about September 30 of this year, will provide overall scientific direction and organizational support for the program. A Steering Committee, drawn from academia, industry, the public, and NIH, will guide the program and play an integral oversight role for the Contractor throughout the project. A working group of the Council, including members of the proposed Steering Committee, will develop detailed recommendations for a plan for research on promising therapeutic strategies for SMA, such as drug development, gene therapy and stem cell therapy. The plan will address all the steps required, ultimately, to develop an IND—Investigational New Drug—application. The implementation of the research plan will be finalized by the Contractor, with guidance from the Steering Committee. The Steering Committee will assist the Contractor in evaluating success in accomplishing milestones, and in developing additional calls for research proposals as needed. Because the role of the Steering Committee is so integral to, and defined by, the contract, it would have been premature to establish its membership in advance of the publication of the statement of work in the request for proposals (RFP) for the SMA program; this RFP was issued on April 22, 2003. Importantly, efforts to recruit the Steering Committee are well underway, and there will be detailed recommendations for the research plan ready for presentation to the Council in September; calls for research projects can be issued in October 2003, shortly after the contract is awarded, and research projects should be underway by February 2004.

The SMA translational program is not just a novel program for SMA, but also for the NINDS. The aim is to develop treatments that will be tested in people, and we hope this effort will serve as a model for expediting therapy development for other disorders. This program will require a significant investment of resources; the contract will be awarded for four years, and NINDS intends to fund the research subcontracts at a level of $4.5 million per year, which we anticipate will fund up to approximately ten research subcontracts per year. The NINDS intramural program will be involved throughout the process, providing expertise in neurogenetics and SMA, and will be equipped to rapidly initiate Phase I/II clinical trials when appropriate. For all of these reasons, careful planning has been essential.

Senator SPECTER. Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman. I have an interest in SMA, also. I have met with families in Iowa about this. And I am concerned, as Senator Specter, that the leading cause of infant mortality is something that——

Senator SPECTER. You ladies and gentlemen would be amazed with how many families we have met with with SMA and the other ailments.

Senator HARKIN. Yes. I started meeting with them maybe a couple years ago in Iowa or something. And this is something I had not even known about before. And now I just—now we find out that it is the leading cause of infant mortality. And we just have not done that much research on it. So I agree with you, we have to push hard on that. We have to get this thing moving. And I do not know why it has not by now. So I agree with the chairman on this, that we have to find out about that.

Senator SPECTER. Well, there is one fellow who suffers from Parkinson's, who has an hourglass. Whenever he sees me, he turns the hourglass. And the ticking sands are going through the hourglass on every hour of his life. And these parents come to us with SMA and other ailments.

I am about to go through a fairly long list of questions. We are going to take a little more time today, because we want to know what the sense of urgency is as to how these issues are being addressed.

These people come to us and say, you are giving NIH all the money. What is happening? I do not like to hear talk of long periods of time on appointing steering committees.

Senator Harkin.

Senator HARKIN. Thank you again, Mr. Chairman.

I understand that you, in my absence—I was unavoidably absent from here a little bit—that you did cover the issue of stem cell research. And I just again want to buttress what you have said and hope that we can move ahead aggressively in this area, too. I understand that has been covered. So I will not go into that.

The only thing that I just wanted to cover with you, Dr. Zerhouni, was just basically broader picture of the funding of NIH. We, as you know, basically just finished the doubling over 5 years. Senator Specter and I are both, with his leadership and with my support, starting to get on another pathway of trying to get it up to a tripling, that is, from what we started in 1998.

To maintain that level, it seems to me we are going to have to have somewhere in the neighborhood of about 7 or 8 percent a year, if I am not mistaken, increases. And it is my understanding, also, that just to maintain and kind of keep doing what we are doing, we are going to need somewhere in that level of funding. And yet the budget request this year is a 2.5 percent request.

So how can we keep from falling back from what we have done? And how can we continue to move ahead with a fairly aggressive level of expansion of NIH basic research at 2.5 percent, or 2.6 percent, I guess it is?

Dr. ZERHOUNI. Thank you.

Senator HARKIN. I mean, my point is, you asked for 2.6 percent.

SUSTAINING RESEARCH PROGRAMS ON MODEST BUDGET INCREASES

Dr. ZERHOUNI. Thank you for your question. This is a very important consideration. Because one of the issues that we have to match with the concept of doubling is why are we doubling? And what are we trying to accomplish? And I think one of the issues that I raised was that we have evolving challenges. We have in fact stimulated in our country an incredible change in the way we do biomedical research. And we are in the transition phase in terms of understanding the new methods of research and the new teams that need to do this research.

When you look at the 2004 budget, I worked very hard with the administration, with the Department, and with the Office of Management and Budget, when you look at the 2.6 percent overall, and we worked so that the effect on our research would be about 7.5 percent overall. And the reason for that is because we have essentially used one-time expenditures that related to building the infrastructures that we needed for biodefense research and other one-time items and reinvested it in research.

So for 2004, the impact on the research portfolio in terms of growth is greater than the 2.6 percent, Senator.

Senator HARKIN. Well, I want to delve into that. In fiscal year 2003, Congress funded more than $300 million for extramural construction with allergies and infectious diseases, bioterrorism.

Dr. ZERHOUNI. $375 million.

Senator HARKIN. $375 million?

Dr. ZERHOUNI. Yes.

Senator HARKIN. I think you can argue that was probably a one-time expense.

Dr. ZERHOUNI. Correct.

Senator HARKIN. But if I look at the extramural facilities renovation and construction program, going back just the last few years, this is an ongoing funding stream that this committee has funded, under different chairmanships here. We have all been supporting extramural construction and renovation. We know that some of the labs around the United States are deficient. They need to be upgraded. I am sure Senator Specter has visited, as I have. And so we embarked on this, also, a few years of making a funding stream every year available.

So how can you say that this is a one-time expense? I could see saying that the $300-and-some million that we put in last year was a one-time expense for bioterrorism. But we have an ongoing extramural renovation and construction program that last year was $119 million, aside from that $300-and-some million. It was $110 million the year before. Now it was $75 million a year for a few years before that. But then we bumped it up, because we saw the need out there. And now in fiscal year 2004, we are requesting zero dollars.

To me, that is not a one-time expense. It is an ongoing commitment that we have to rebuild and modernize our laboratory infrastructure in the United States.

FUNDING COMMITMENT TO EXTRAMURAL CONSTRUCTION

Dr. ZERHOUNI. For the 2004 year, what we tried to do was to preserve and maintain the momentum in what is the most critical resource, and that is people applying for grants and getting support so that the teams of the scientists that we have stimulated continue to be stimulated. So we had to make hard choices, Senator. And that is one of them.

Senator HARKIN. But if we make the choice here to continue to fund extramural construction, then you will not have that money for research, will you? It will be down to 2.6 percent.

Dr. ZERHOUNI. That is——

Senator HARKIN. If we keep the level of funding——

Dr. ZERHOUNI. In each category the same per year, you are correct. You are correct, Senator.

Senator HARKIN. Dr. Zerhouni, are you advising us that we should zero out all funding for renovation and building of laboratory facilities?

Dr. ZERHOUNI. For the year 2004, because of the portfolio of construction that we had to do and that we had to continue to fund, we thought that the best strategy to maintain the research momentum so that we can invest it in programs that relate to diseases was to make that choice and——

Senator HARKIN. For next year.

Dr. ZERHOUNI. For next year. Correct.

Senator HARKIN. Well, then, Dr. Zerhouni, let me carry this one step further. The President's budget documents call for a 1.9 percent increase in 2005, a 2 percent increase in 2006, and 2.2 percent in 2007. So carrying this logic forward, then for the next 3 years, we will be asked to zero out any funding for extramural construction and renovation, if that is the case. So it may be so next year. We may be looking at 4 or 5 years here——

Dr. ZERHOUNI. Right.

Senator HARKIN [continuing]. Of zeroing out any—I do not—I can only speak for myself, but to me that is unacceptable. We cannot do that. And so I just—you know, this idea that somehow we are going to squeeze out of this and get a 7 percent for basic research and to make sure we keep the grant funding going out at that level, it does not square with what we have to do with extramural construction.

So I—maybe you might do it 1 year. I do not think you can. I think we just cannot go to zero funding for 1 year. We can cut out the $300-and-some million, because that was a one-time expenditure for bioterrorism. But then there is the underlying program that I do not think that we can cut out. So I just wanted to make that point. I know what you are trying to do, but I do not think it fits. And we are simply going to have to come up with that extra money. And I am going to keep proposing that the President has to put that in his budget next year.

Thank you, Dr. Zerhouni.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Harkin.

Dr. Zerhouni, I am going to go over a series of questions. We have been asked to have separate hearings on many of the insti-

tutes. And that is not possible, given all of the difficult schedules. We have been asked to have a separate hearing on tuberous sclerosis, where scientists have reportedly isolated the genes responsible for this disease that affects all of the body's organs.

I would like you to submit in writing and in some detail how much NIH is currently investing in research on tuberous sclerosis, and how that research is being coordinated among the various institutes involved.

[The information follows:]

TUBEROUS SCLEROSIS COMPLEX

The NIH reported actual funding for tuberous sclerosis research in fiscal year 2002 was $6.1 million; the fiscal year 2003 estimated funding is $6.4 million. While the National Institute of Neurological Disorders and Stroke—NINDS—is the lead institute for research on tuberous sclerosis complex, TSC, several other institutes conduct and support TSC research, which is reflective of the multiple organs affected. The National Cancer Institute—NCI; the National Heart, Lung, and Blood Institute—NHLBI; and the National Institute of Diabetes and Digestive and Kidney Diseases—NIDDK, support TSC research. Funding by Institute is summarized in the table that follows:

	Fiscal years		
	2002 actual	2003 estimate	2004 estimate
NCI	$638,000	$657,000	$677,000
NHLBI	2,140,000	2,279,000	2,336,000
NIDDK	717,000	700,000	700,000
NINDS	2,596,000	2,803,000	2,859,000
OD	30,000	.....	.....
Total	6,121,000	6,439,000	6,572,000

The systems affected in TSC are quite distinct, and therefore, much of the research supported may be unique to a particular institute's mission, for example, NINDS to investigate the development of epilepy and autism in children with tuberous sclerosis; NCI for studies to examine what causes skin tumors to develop in patients with TSC; and NHLBI to study the molecular and cellular basis for the development of lymphangioleiomyomatosisL—AM—a severe destructive lung disease, in patients with tuberous sclerosis complex. However, we recognize the value in tracking and coordinating the TSC research that NIH supports, as well as identifying potential partnering opportunities, and on this NINDS has the lead. Coordination is achieved in many ways, not the least of which is regular communication among the program directors who manage the TSC portfolio in each institute. In addition, NINDS is coordinating input from several institutes, extramural researchers, and the advocacy community in developing the NIH research plan for tuberous sclerosis. For example, program staff from NIDDK and the National Institute of Arthritis and Musculoskeletal and Skin Diseases—NIAMS—participated in the September 2002 NINDS-sponsored workshop on TSC research, the proceedings of which are providing the framework for the research plan, and these institutes, along with the National Institute of Child Health and Human Development—NICHD, NHLBI, and NCI, are being consulted in the development of the NIH TSC research plan.

Senator SPECTER. There is another subject matter of scleroderma, where there has been a tremendous amount of interest. And there is significant vascular and autoimmune components to scleroderma. And the question is whether there are other institutes, aside from the National Institute of Arthritis, Musculoskeletal, and Skin Disorders or the National Heart, Lung, and Blood Institute, that you would recommend scleroderma researchers pursue to find experiments aimed at finding a cure.

Since the leading cause of death in scleroderma patients is through pulmonary hypertension and its effects on heart function,

should grants on pulmonary hypertension that encompass issues unique to scleroderma patients be directed at—and this question goes to Dr. Katz and Dr. Lenfant. Should those research grants be directed at NHLBI, instead of NIAMS?

These questions are so complicated that I have to read them, which is not my style.

What do you think, Dr. Lenfant? Are you willing to defer that to another agency, or should they be directed to your agency? I would appreciate as much brevity as you can bring here, because there are quite a few more questions. And we need to finish this hearing by 11. Actually, we need to finish this hearing by 10:45.

SCLERODERMA RESEARCH

Dr. LENFANT. Senator, in view of the complexity of this condition, I think the research must be conducted by the two institutes. And it is so happens that Dr. Katz and I work very well on many conditions besides this one. And I am quite confident that this cooperation, should it continue, it will be the best way to handle that condition.

Senator SPECTER. How are you doing, Dr. Lenfant, on finding a cure for scleroderma?

Dr. LENFANT. Scleroderma, or systemic sclerosis, is of considerable interest to the NHLBI because of the lung problems that so often accompany it. Indeed, 8 out of 10 patients with scleroderma eventually develop some degree of lung disease, and interstitial pulmonary fibrosis (scarring) is now the leading cause of death among such patients. Since 1999, the NHLBI has supported the Scleroderma Lung Study, a clinical trial to evaluate treatment with cyclosphosphamide, a drug that has effects on inflammation and the immune system. The goal is to determine whether cyclophosphamide helps stabilize or improve measures of lung function; the trial will also assess changes in quality of life, activity, and shortness of breath. A positive outcome of this trial would be of great importance by offering a scientific basis for treatment. Similarly, a negative result, demonstrating no benefit from cyclophosphamide therapy, would provide an important basis for avoiding a hazardous and expensive therapy that is now being used in many patients.

SCLERODERMA

Senator SPECTER. Dr. Katz, how close do you think you are coming to finding a cure for scleroderma?

Dr. KATZ. We are pursuing every scientific opportunity possible in scleroderma research and working with the community as well as with our colleagues at NHLBI in this area, which includes pulmonary fibrosis. We are pursuing research on blood vessel abnormalities genetic controlled fibrosis, as well as other genetic dimensions of scleroderma. So we are pursuing——

Senator SPECTER. Is it a realistic question to ask you how close you are to a cure?

Dr. KATZ. Yes, sir. It is a realistic question.

Senator SPECTER. Can you give me a realistic answer?

Dr. KATZ. I cannot give you a date, if that is what you are looking for. But I——

Senator SPECTER. Can you give me a time frame, a ballpark?

Dr. KATZ. I would hope that in the next 5 years we will have some better information on the complexity of this disease.

Senator SPECTER. Sometime within the next 5 years we would have better information on the complexity of the disease.

Dr. KATZ. Right.

Senator SPECTER. I would like you to supplement that in writing, focusing on my question, please.

Dr. KATZ. I would be happy to.

[The information follows:]

SCLERODERMA

I am very pleased to tell you that research on scleroderma is at a very important and promising juncture. We have a solid foundation of grants in our portfolio, we have very powerful research tools to apply to scleroderma, and we are building on significant research advances in our understanding of scleroderma. Examples of recent advances include identifying a genetic marker for scleroderma in two populations; basic research that identified defective microfibrils in cultured fibroblasts from people with scleroderma; and the determination that the risk of having scleroderma increases significantly (on the order of 10 to 27 times) if a family member has scleroderma. These are just highlights of progress. With a look to the future, I am very optimistic that within the next 5 years we will have much better information on the complexity of scleroderma. My optimism is based on the multi-pronged approach that we have taken in research on scleroderma, including the ongoing, 5-year, multicenter clinical trial that is seeking to determine the efficacy of oral collagen in the treatment of scleroderma; the funding that the NIAMS provides for two Specialized Centers of Research focused on scleroderma that will enhance translational research; support for the National Family Registry for Scleroderma that will provide vitally important information on the genetic/family dimensions of this disorder; and the outcomes of the 10 new research grants that the NIAMS funded in fiscal year 2001 as the result of a special solicitation. We can expect that research findings will begin to emerge from these grants over the next few years and will contribute significantly to our understanding of the complexity of scleroderma. In addition, I would note that scleroderma is an autoimmune disease, and the knowledge base in this area is progressing at a rapid pace. Findings that we learn from one autoimmune disease can be very useful in informing us about other autoimmune diseases. So if we look broadly, advances in genetics and autoimmunity will accelerate the pace of progress in scleroderma and many other diseases. We know that medical research is an investment, and I believe that the investments we have made over the last few years will provide critical, key pieces of the multi-dimensional, challenging puzzle that scleroderma represents.

Senator SPECTER. Dr. Zerhouni, we are having a lot of comments on the Muscular Dystrophy Care Act, which called for the creation of multiple centers of excellence, signed into law in 2001. That was before your watch. The subcommittee on three occasions has said that a minimum of three such centers should be funded. A request for proposals has finally gone out to organize the centers. But the only assurance of the scientific community is that two centers will be funded.

I would like you to submit in writing an answer to the question, why only two? And what funding level is projected for these centers?

[The information follows:]

MUSCULAR DYSTROPHY

The NIH has been actively engaged in implementing the mandates of the MD-CARE Act, including efforts to establish research centers for muscular dystrophy. Specificially, in the Fall of 2002, the NIH issued two Requests for Applications (RFAs) in this area. The first solicited applications for up to three awards for Muscular Dystrophy Cooperative Research Centers, and the second solicited applications

for up to five awards for Developmental Planning Grants for future centers. During fiscal year 2003, following peer review, we will make grant awards in response to these two RFAs; the number of grants actually awarded, up to the specified numbers, will depend on scientific merit. In fiscal year 2004, we plan to re-issue the RFA for Cooperative Research Centers, and expect to fund up to two additional meritorious centers in fiscal year 2005. Subject to the number of applications we receive and the results of scientific peer review, the combined solicitations could result in funding up to a total of five MD cooperative centers.

We anticipate that the total costs for each center will be approximately $1.5 million for 5 years. If the combined solicitations result in funding a total of five MD cooperative centers, the total costs of all centers for 5 years is estimated at $37.5 million.

Senator SPECTER. A question to the Cancer Institute to be responded to by Dr. von Eschenbach. On June 21, 2001, we held a hearing on blood cancers. And Dr. Klausner, then the Director of the Cancer Institute, testified that Gleevec has shown remarkable results in treating chronic leukemia. The question is: Why is Gleevec only effective on this particular form of cancer? And in what specific ways would Federal funding of stem cell research expedite the treatment and cures of blood cancer?

GLEEVEC

Dr. von Eschenbach, would stem cells be helpful there, stem cell research?

Dr. VON ESCHENBACH. Thank you, Senator. As you are well aware, there has been a great deal of research with regard to adult stem cells, and particularly in their application therapeutically in support of the treatment of blood cancers. The issue of Gleevec, that is a very important story. Because one of the wonderful things that we have seen as a result of the progress made in using a drug like Gleevec, targeted to a specific genetic defect in leukemias, the understanding of how that drug works in that pathway is now being extended to a whole variety of other cancers. Gleevec is being used in prostate cancer and it is being used in other childhood cancers. So the return on investment of Gleevec is going far beyond the blood cancers.

Senator SPECTER. Dr. Insel, the prevalence of autism is increasing, with the disease affecting, as we understand it, some 500,000 people in this country at a cost of $13 billion annually. Autism advocates are requesting the NIH expand its research portfolio as well to finance a tissue bank program that would enhance resources and provide centralized tracking of research projects among all autism research participants.

What are your plans to develop a tissue bank? And how much has autism research increased since the NIH doubling began?

AUTISM RESEARCH

Dr. INSEL. Thank you, Senator. The interest in the autism tissue bank has increased greatly in the last few months. We held a workshop just in the last 6 weeks, bringing——

Senator SPECTER. Greatly? Greatly?

Dr. INSEL. Yes.

Senator SPECTER. How much?

Dr. INSEL. In terms of the interest? There is a wide——

Senator SPECTER. Increase in funding is the question.

Dr. INSEL. I was saying interest in the tissue bank. The workshop that we held 6 weeks ago brought in people from around the country who are experts in autism. There is a plan to roll out the specifics at the next Interagency Autism Coordinating Committee meeting.

Senator SPECTER. Is a tissue bank now being developed?

Dr. INSEL. We anticipate it will be public by July, the first week in July.

Senator SPECTER. And how much has autism research increased?

Dr. INSEL. In 1998, the NIH budget for autism was $26,889,000. In 2002, it was $73,850,000.

Senator SPECTER. Dr. Fauci, let us come back to smallpox one more time. The Federal Government is not recommending vaccination for the public. But HHS has stated that it will try to accommodate members of the public who want to be vaccinated. As the program is projected this year, the public has two options. First, enrolling in ongoing clinical trials; or second, for those who want to be vaccinated but who do not meet the trial criteria, HHS has proposed that it will allow vaccinations under an investigational new drug approach, which will require informed consent.

Now this is because the new vaccine has not yet been licensed. Once the new vaccine is licensed in 2004, concluding that it will be at that time, the only way the public will be able to get it is from HHS.

My question to you is, vaccination for the general public is at the impetus of the individual. Do you think this is sufficient, or should there be a national vaccination strategy for the general public as opposed to waiting for the individual to come forward?

NATIONAL VACCINATION PROGRAM

Dr. FAUCI. Mr. Chairman, given the current threat assessment, I think a national vaccine program for the general public, beyond just someone coming and asking for it, is not necessary at this time. The first priority, as you know, is to vaccinate the core smallpox response team and ultimately the first responders.

But given the current threat assessment, if we get that core group vaccinated, which we hopefully will, then in the event of an attack, the logistic capability of vaccinating anyone who is within the range of a contact would be much easier than it is right now. So the combination of the Department of Homeland Security and HHS have come to the judgment that we do not need to implement a pre-event program for the general public at this time.

Senator SPECTER. Dr. Fauci, I hope you are right.

Dr. FAUCI. I hope so.

Senator SPECTER. We have gone back and forth. We have had quite a number of hearings on the subject. We have talked about our grandchildren. There is no precise, cannot be a precise, evaluation of what the risk is of a smallpox attack, try to use that as a biological warfare weapon. People who have taken the vaccine with some bad results. People do not like the risk. Pretty tough to undertake a risk from the vaccination when there is no identifiable risk of bioterrorism in the field.

Dr. FAUCI. Right.

Senator SPECTER. But at the moment, the policy is sort of—perhaps it is not drifting along, but it is pretty hard to formulate it with precision. But I respect your conclusion that the policy has been thought through. And you have decided to do no more. But we all hope you are right that we do not find a bioterrorism attack and insufficient cautions having been taken.

Dr. FAUCI. Excuse me, sir. In the event of an attack, there is a response capability that we are building on right now that would very likely, almost certainly, be able to protect the country. The reason that the program has not been recommended for the public is because the threat assessment of an attack is balanced against the known toxicities of the currently available Dry Vax, and it is felt that a preemptive total vaccination of the Nation is not necessary.

This will change if one of two things happen. If the threat assessment changes and we feel the threat is greater. And what we are striving for in the next couple of years is a smallpox vaccine that has many fewer toxicities or adverse events. If we had the attenuated vaccine at the current time, I believe there would be a good deal more flexibility in the broad general recommendations for the general public.

Senator SPECTER. Well, thank you very much, ladies and gentlemen. This is the longest hearing we have had in awhile. We are into the third hour. And it is hard to attract the attention of Senators for very long around here, given the problem of the war in Iraq and what we are going to do with North Korea and how we are going to handle the Middle East and what we are going to do with terrorism and what we are going to do with double taxation of dividends, probably the foremost question on the minds of everybody in this room today. I mean, not the foremost question on the minds of everybody in this room today.

We appreciate what you are doing. There are going to be questions submitted for the record. And when Senator Taylor calls you up and brings issues to your attention, she is speaking for the whole Congress. She does not speak for just herself.

She does not speak just for me. She does not speak for Senator Harkin and me or this subcommittee or the full Appropriations Committee or the Senate. She speaks for the whole Congress.

We have become a lightning rod for inquiries and demands. You have no idea how many irate parents we see, or irate children we see for interest in their parents. So if we convey a sense that we are looking for a greater sense of urgency, if you get that message today, you are right. But we do know that you are in the trenches doing very, very important work. And we have a tougher issue now than we have ever had before on finding the money for NIH and the CDC. But we are going to plug away. And we look for your continued success.

ADDITIONAL COMMITTEE QUESTIONS

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED TO THE NATIONAL INSTITUTES OF HEALTH

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

PANCREATIC CANCER

Question. Director von Eschenbach, this Subcommittee has taken a keen interest in the status of pancreatic cancer research at your Institute. Pancreatic cancer is the now the 4th leading cause of cancer death for men and women in this country. It also has the highest mortality rate making it the cancer you are most likely to die from, if you are diagnosed with this disease, because of the lack of reliable diagnostics.

I would like for you to update the Subcommittee on the status of a number of pancreatic cancer initiatives:

Last year's report expressed the strong intent of this Committee that the NCI fund at least five Pancreatic Cancer Specialized Program of Research Excellence (SPORE) grants by fiscal year 2004. Will you be following the Committee's intent—as expressed in last years report language—to fund five Pancreatic Cancer SPORE Grants by fiscal year 2004?

Answer. In fiscal year 2004 NCI expects to fund three pancreatic cancer SPORE grants. The NCI announced a special initiative to enhance and promote translational research in pancreatic cancer and received fourteen pancreatic SPOREs applications. Thirteen of these applications were reviewed by a Special Emphasis Panel following general peer-review principles established by the NIH. Only three of these SPORE applications were found to have sufficient scientific merit to be considered for funding by the NCI. No definitive decisions can be presented at this time since our funding recommendations will undergo a second level of review by the National Cancer Advisory Board at the next meeting in June 2003. We anticipate these three meritorious applications will be funded as P20 Development awards. We are hopeful these preliminary programs will jump start the field and serve as a foundation to develop additional strong researchers and programs in this field.

Question. How many of the meritorious individual projects from non-funded SPORE Grants and program project applications does the NCI intend to fund in fiscal year 2004?

Answer. Four projects from the remaining applications were considered by the peer review as highly scientifically meritorious. These applications will be recommended for submission to our R01 grant mechanism for individual funding.

Question. I compliment the NCI's past efforts to increase the paucity of researchers through extending the payline for grants that were 100 percent relevant to pancreatic cancer. I understand that this initiative may have been the single most important action taken by the NCI to finally give pancreatic cancer the support that it needs, yet it was discontinued after just one year. Why was this important payline initiative discontinued?

Answer. Extending the payline for applications that were 100 percent relevant to pancreatic cancer enabled the NCI to fund only three additional pancreatic cancer research projects in fiscal year 2002. The NCI discontinued the extended payline for pancreatic cancer applications in fiscal year 2003 and agreed to use a mechanism for exception funding to include grants that meet only 50 percent relevancy. The NCI remains firmly committed to increasing the amount of research focused on pancreatic cancer. Therefore, the NCI is granting pancreatic cancer applications higher priority for exception funding, even those with only 50 percent relevance to the disease. We are hopeful that this mechanism will significantly increase the number of meritorious grants that will impact on pancreatic cancer.

Question. Do you have plans to reinstate this extended payline, and what are the estimated costs to continue it for a period of five years?

Answer. Since extending the payline for pancreatic cancer applications reduced the number of better scoring applications that the NCI could fund, the NCI does not intend to reinstate the extended payline. This decision is not made on basis of cost but rather a strategic effort to encourage meritorious research relevant to pancreatic cancer.

Question. If not, how do you intend to develop the critical mass of researchers needed for pancreatic cancer?

Answer. In its recently released strategic plan for addressing the recommendations of the Pancreatic Cancer Progress Review Group (http://prg.cancer.gov/pancreatic/pancreatic.pdf), the NCI lays out a multi-faceted approach for developing a critical mass of pancreatic cancer researchers. The Institute has implemented some of the strategies in the plan already. These include:

—Granting special consideration to pancreatic cancer applications beyond the payline, even those with only 50 percent relevance to the disease.
—Soliciting and promoting applications for SPOREs in pancreatic cancer. The top-scoring applications will undergo a required second level of review by the National Cancer Advisory Board in June.
—Informing investigators of new funding opportunities in areas of particular relevance to pancreatic cancer, such as host-tumor interactions, the tumor microenvironment, and nanotechnology development for early detection.

NCI plans to put additional strategies in place in fiscal year 2003 and fiscal year 2004, but actual implementation will depend upon a final determination that these strategies are feasible and sound, and the receipt of high-quality applications from the research community. These strategies include:

—Expanding the Transition Career Development Award (K22) to extend the funding period and include all scientists.
—Increasing the number of pancreatic cancer research mentors through the National Research Service Award program.

Question. It is my understanding that the NCI is continuing to make good on its commitment to implement the report of the Pancreatic Cancer Progress Review Group (PRG)—which is a national agenda for the research needed on pancreatic cancer. I have been told that since the PRG Report came out in February 2001, the NCI has been moving forward to implement the suggestions raised in the report, and that most recently the NCI has developed a "Strategic Plan for Addressing the Recommendations of the Pancreatic Cancer Progress Review Group" to further detail and prioritize the research needed on this disease. With the President's proposed NIH increase of roughly 2.6 percent for fiscal year 2004, how many of the strategies identified in the "NCI Strategic Plan" can actually be put into place next year, and which ones do you plan to implement?

Answer. The NCI has already implemented some of the strategies in its pancreatic cancer plan. These strategies include:

—Granting special consideration to pancreatic cancer applications beyond the payline, even those with only 50 percent relevance to the disease.
—Soliciting and promoting applications for Specialized Programs of Research Excellence (SPOREs) in pancreatic cancer.
—Funding the development of new pancreatic cancer mouse models.
—Funding phase 1 and phase 2 studies for chemoprevention of pancreatic cancer.
—Holding a state-of-the-science meeting on management of pancreatic cancer symptoms.

NCI plans to put additional strategies in place this year and next, but actual implementation will depend upon a final determination that these strategies are feasible and sound, and the receipt of high-quality applications from the research community. These strategies include:

—Funding the development of nanotechnologies that use small samples for early detection of pancreatic cancer.
—Identifying markers for early detection of pancreatic cancer through NCI's Center for Proteomics.
—Funding research on normal pancreas biology and pathogenesis of pancreatic cancer (with NIDDK).
—Expanding NCI's cohort consortium to include pancreatic cancer.
—Supporting large case-control studies in HMOs to improve understanding of pancreatic cancer risk factors.

Question. I know the request was made before you came to the NCI, but in the fiscal year 2002 report, this Committee specifically requested that the NCI develop a professional judgment budget due April 1, 2002 for research on pancreatic cancer for the next five years. The goal here was to ascertain how much the NCI is actually spending on pancreatic cancer and compare the current funding level to what is actually needed to make some inroads on this disease, which has a 99 percent mortality rate, making it the cancer you are most likely to die from, if you are diagnosed with this disease. While I am delighted to hear that movement is being made on the findings of the Pancreatic Cancer Progress Review Group, we have not received the Five-Year Professional Judgment Budget to implement these recommendations. When might we receive it?

Answer. Over the past several years, NCI has convened Progress Review Groups (PRGs) on several types of cancer, and the reports generated by these groups have formed the basis of expanded and intensified research in these areas. Completed PRG reports have identified gaps in research in breast, prostate, colo-rectal, brain, pancreatic, hematologic, lung, and gynecologic cancers. As with all other PRGs, NCI developed an implementation plan to move forward with the recommendations for

pancreatic cancer research in a prioritized fashion. This was done with participation by outside scientists and advocates who also participated in the PRG itself.

NCI announced a 10-point plan of action that allows NCI to take immediate steps to address the gaps in pancreatic cancer research. Some strategies have already been implemented such as granting special consideration to pancreatic cancer applications beyond the payline and funding Specialized Programs of Research Excellence (SPOREs) in pancreatic research. The plan's approach involves expanding existing programs, as well as developing new initiatives. Additional strategies are being considered, including funding the development of mechanisms for early detection and expanding proteomics research.

We estimate that we will spend $38 million on pancreatic cancer research in fiscal year 2004. The preparation of a Professional Judgement Budget will take into account the implementation of these programs and their expected expenditures and increases over the next five years. Subsequent initiatives will be included in a rolling forward budget plan as reflected in our Bypass Budget.

PROTEMOMIC PATTERNS

Question. In last years report, this Committee encouraged the NCI to "rapidly identify predictive proteomic patterns relevant to pancreatic cancer" and "to develop and implement methods for rapid case ascertainment." Can you please provide us with the status of progress in both of these areas including what has been developed and implemented?

Answer. The body's 30,000 or so genes carry the blueprint for making proteins, of which all living matter is made. Each protein has a particular shape and function that determine its role in the body. NCI has an extensive research program in proteomics, the study of protein shape, function, and patterns of expression, in hopes of developing better prevention, screening, and treatment options.

There has been a joint effort including the Food and Drug Administration (FDA), the NCI Clinical Proteomics Program, and Correlogic Systems Inc. which has brought together two scientific disciplines: proteomics and artificial intelligence computer programs.

Last year, there was an exciting announcement that with a preliminary diagnostic test, which could be completed in 30 minutes using blood that can be obtained from a finger stick, researchers were able to differentiate between serum samples taken from patients with ovarian cancer and those from unaffected individuals. Further study is continuing to confirm the sensitivity and accuracy of this technique as a diagnostic tool. The hope is that by combining the proteomic approach with other methods of ovarian cancer diagnosis, such as ultrasound, its accuracy can be further improved. This new diagnostic concept is potentially applicable to any type of disease and is now being tested on pancreatic, prostate, lung and breast cancer.

NCI has made significant progress in the early detection of pancreas cancer using serum proteomic patterns. We are pleased to have already made progress in the application of this technology to pancreatic cancer. Scientists tested 350 plasma samples from the University of Minnesota. The sample groups were (a) unaffected, (b) diabetes only, (c) pancreatitis only and (d) pancreatic cancer. NCI researchers discovered a serum proteomic pattern that was greater than 95 percent sensitive and specific in the classification of pancreas cancer compared to the other non cancer groups. Currently there is no other reliable test for pancreas cancer. We are now moving forward to validation of these preliminary results in a larger population of patients with and without pancreatic cancer. At the same time we are applying this technology to other cancers. If validated in larger series serum, proteomics could constitute a new approach to the early diagnosis of pancreatic cancer.

COMPREHENSIVE CANCER CENTER PROGRAM

Cancer is a disease that affects families of all backgrounds in all parts of the country. However, cancer affects more families in my state than most others. We hold the unfortunate distinction of ranking among the top five in the nation in rates of multiple myeloma and oral, prostate, pancreatic, and esophageal cancer. We are also not far behind in regard to cervical and larynx cancer.

Through the significant investment this Subcommittee has made in cancer research, we have enabled scientists from across the country to expand our basic understanding of cell growth and death and to develop effective forms of treatment and prevention. Much of this work was accomplished in NCI-designated comprehensive cancer centers. I am troubled that these centers tend to cluster in the Northeast and along the Pacific Coast, and bear little correlation to cancer incidence or mortality rates. In fact, only three of the fifteen states with the highest cancer mortality rates have a comprehensive cancer center. While we should continue to fund the

best and brightest in their efforts to find cures for cancer, I believe the current concentration of comprehensive cancer centers deprives us of gaining valuable knowledge in the parts of the country where cancer is most prevalent.

Question. Director Zerhouni and Director von Eschenbach, I would like to hear your plans for how you intend to grow the comprehensive cancer center program and how you intend to ensure that areas with high cancer rates receive the full attention of these centers.

Answer. At the present time, NCI has 60 clinical and comprehensive cancer centers. They have a wide geographic distribution and leverage the extraordinary talents and resources of major medical centers. These spheres of influence go far beyond their geographic location as a Center of Excellence of cancer treatment.

Over the years, the NCI has worked closely with a number of smaller institutions in underrepresented areas through the P20 planning grant program. At the present time, six centers are recipients of planning grants. Four of these are in states that currently have no cancer center and a fifth serves a primarily minority population. We are developing mechanisms to promote consortium centers in areas where one institution does not have the capability to apply independently, with concordant revision of NCI requirements to accommodate their unique structure. In at least one state, such a consortium has received legislative support and funding.

The NCI's Special Populations Network program is establishing a robust and sustainable infrastructure to promote cancer awareness within minority and medically underserved communities, and launching more research and cancer control activities aimed at specific population subgroups. The current Special Populations Networks consists of 18 projects in 15 states across the United States. Initial projects were begun after funding was awarded in April 2000 to groups that addressed ways of building relationships between large institutions and community groups. During the first year, cancer awareness projects were implemented in the community and project plans were developed. In the second and third years, partnerships between the project and NCI sponsored groups should enhance minority training and minority participation in cancer trials. In the last two years of these awards, full-fledged investigator-initiated research grant applications will be developed based on the initiative projects.

The NCI is also considering other options to improve access of patients in underserved areas to the benefits of cancer research. One such concept is that of a Regional Enhancement and Cancer Community Health (REACH) initiative, which would pair smaller institutions in these areas as formal partners with existing NCI designated centers for collaborative research activities and delivery of cutting edge care. As currently envisioned, this would involve providing small grants to the smaller centers for encouragement of research, as well as some form of NCI designation. An additional alternative might be to provide moderate support for the existing affiliate networks already established by the centers. These networks are primarily focused on clinical care but additional support could be provided to specifically foster the more extensive delivery of clinical trials into the community setting.

Finally, through the emphasis of the NCI on the "Discovery, Development, Delivery" continuum, we anticipate that links between existing Cancer Centers, their affiliates and partners in research, and the state, municipal and private organizations within their communities will continue to expand. These links, once firmly established, should result in a more unified approach to the conquest of cancer, and a more uniform delivery of the benefits of cancer research into the community. NCI is actively seeking mechanisms to foster both the vertical integration (i.e. from the cancer centers through the community layers they serve) and the horizontal integration (i.e. across cancer centers and a nationwide network of public and private partners) of the benefits of cancer research.

SJÖGREN'S SYNDROME

Question. Some progress has been made regarding Sjögren's syndrome at the NIAID. However, the NIAMS conducts research on closely related diseases such as lupus, scleroderma and rheumatoid arthritis. Are you conducting research on Sjögren's syndrome and are you coordinating this research with other Institutes at the NIH?

Answer. In collaboration with the NIAID and the NIDCR, the NIAMS supports research on Sjögren's syndrome and other autoimmune diseases that ranges from basic science investigations to genetic studies to prevention research. The NIH Autoimmune Diseases Coordinating Committee, of which the NIAMS is an active member, helps ensure the coordination of effort among various Federal and private entities that conduct autoimmunity research, education, and outreach. The NIAMS funds work to better understand the molecular basis of autoimmune diseases such

as Sjögren's syndrome; to identify genes that predispose individuals to autommunity; and to develop animal models which will provide insights into the human form of diseases such as Sjögren's.

STEM CELL RESEARCH

Concerns have been raised by some in the scientific community that not all NIH institutes are aggressively pursuing a stem cell research agenda.

Question. Would you please submit for the record how each of your institutes and centers has been implementing the embryonic stem cell research policy?

Answer. In November 2001, NIH issued NOT–OD–02–005 Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells (hESCs) and Establishment of NIH Human Embryonic Stem Cell Registry. This notice describes how federal funds can be used to support research in human embryonic stem cells that meet the criteria established by the President. This Notice also references the NIH Stem Cell Registry—a registry that only lists those human embryonic stem cell lines that meet the eligibility criteria. All NIH institutes comply with points described in the Notice and for those that support human embryonic stem cell research, only support human embryonic stem cell research that uses cell lines listed on the NIH Stem Cell Registry. In addition, NIH has a Stem Cell Implementation Committee with representatives from the NIH Institutes that assists with implementation. This Committee works in tandem with the NIH Stem Cell Task Force to ensure that policy and major research initiatives are communicated to all Institutes and provide a means for inter-Institute cooperation and exchange.

Complimenting these NIH-wide implementation efforts are many Institute-specific Program Announcements (PAs), Requests for Applications (RFAs), scientific workshops, and outreach efforts to encourage and support research on human embryonic stem cells. The NIH-wide and Institute-specific initiatives are described for each Institute with portfolios relevant to human embryonic stem cells:

The National Institute on Aging (NIA) is encouraging and supporting research on human embryonic stem cells through a number of Program Announcements, Requests for Applications, Requests for Proposals, and workshops. NIA is co-sponsoring with other NIH Institutes PA 02–054 Short-Term Courses in Human Embryonic Stem Cell Culture Techniques, PAR 02–023 Human Embryonic Stem Cell Research Resource Infrastructure Enhancement Award, and PA–02–025 Plasticity of Human Stem Cells in the Nervous System. In addition, PAR 03–056 NIA Pilot Research Grant Program specifically encourages stem cell research pilot projects and NIA has issued a Request For Proposal (RFP) 260–03–16 on Characterization of Human Embryonic Stem Cell Lines to establish a contract to develop, maintain, and distribute data on the properties of undifferentiated human embryonic stem cell lines. The NIA intramural program is supporting one of the six intramural labs conducting research on human embryonic stem cells. Within NIA, a Stem Cell Working Group meets regularly to disseminate policy information on receipt, tracking, review and administration of grants involving human embryonic stem cell lines, as well as to plan and implement activities involving support of human embryonic stem cell research. In May 2003, NIA is hosting a meeting on Stem Cells and Aging to promote exchange and enhance research among NIA stem cell research grantees.

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is encouraging research on human embryonic stem cells and has issued an RFA 02–010 on Alcohol and Stem Cells that encompasses research objectives that include human embryonic stem cell research.

The National Institute of Allergy and Infectious Diseases (NIAID) is working to ensure that the scientific community has every opportunity to advance research into the potential of human embryonic stem cells in accordance with federal policy. NIAID is co-supporting with other NIH institutes PA 02–054 Short-Term Courses in Human Embryonic Stem Cell Culture Techniques and PAR 02–069 Career Enhancement Award for Stem Cell Research. In addition, new research grant mechanisms are available to support human embryonic stem cell research: PA 02–038 NIAID-Investigator-Initiated Small Research Grants (R03) and PAS–02–160 Application of Exploratory/Developmental Technologies to NIAID-Funded Research (R21). NIAID also accepts and supports requests for administrative supplements to add human embryonic stem cell research to an existing NIAID grant.

The National Institute on Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is encouraging research on human embryonic stem cells through several Program Announcements and Requests for Applications with research objectives that could encompass the use of human embryonic stem cells. These initiatives include: PA 03–009 High Risk Rheumatic And Musculoskeletal And Skin Diseases Research; RFA 02–003 Basic And Applied Stem Cell Research For Arthritis And Mus-

culoskeletal Diseases; PA 02–136 Precursor Cells in Skeletal Muscle Repair and Hypertrophy; and PAR 02–030 NIAMS Small Grant Program for New Investigators. In addition, administrative supplements to an existing NIAMS grant may be requested for the addition of studies of human embryonic stem cells.

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) is fully aware of the policies and procedures governing the funding and use of human embryonic stem cell research and takes the necessary steps to keep grantees informed. Scientific workshops are held and talks are presented to a wide variety of audiences in academia and private industry, concerning tissue engineering, biomaterials, sensors and other areas of research that may include human embryonic stem cells. Recent outreach efforts included presentations at a PGH Engineering Tissue Growth meeting and at a meeting for BEACON, a bioengineering consortium in New England. At every appropriate outreach opportunity, human embryonic stem cells research policy is delineated to current and potential researchers. Training workshops for current and potential grantees address this issue as well. The NIBIB currently has two Requests for Applications, RFA 03–09 Development of Advanced Biomaterials and RFA 03–010 Research Opportunities in Tissue Engineering that request grant applications related to tissue engineering, which may include human embryonic stem cell research.

The National Cancer Institute (NCI) actively encourages research on human embryonic stem cells and widely disseminates NIH policies and procedures to grantees. In addition, NCI is co-sponsoring with other NIH institutes supporting the Program Announcement, PAR 02–054 Short-Term Courses in Human Embryonic Stem Cell Culture Techniques, which provides funding to develop, conduct, evaluate, and disseminate short-term courses on laboratory research techniques for human embryonic stem cell lines.

The National Institute of Child Health and Human Development (NICHD) actively encourages and supports research on human embryonic stem cells. The Institute has implemented the embryonic stem cell research policy through the issuance of special NICHD initiatives in the form of Requests For Applications, Program Announcements and Notices that include embryonic stem cells as potential targets for research. These include: RFA 02–018 Female Health and Egg Quality; RFA 02–029 Specialized Cooperative Centers Program in Reproductive Research; PA 01–005 Reproductive Genetics; NOT 03–005 NICHD Administrative Supplements for Human Embryonic Stem Cell Research. NICHD is also co-sponsoring with other NIH Institutes two program announcements: PAR 02–054 Short-Term Courses in Human Embryonic Stem Cell Culture Techniques, and PAR 02–023 Human Embryonic Stem Cell Research Resource Infrastructure Enhancement Awards to help build the infrastructure and capacity to disseminate human embryonic stem cells eligible for federal research support. In addition, NICHD funded the first formal training course on human embryonic stem cells that was held at the Jackson Laboratory, Bar Harbor, Maine in August 2002. NICHD has also conducted numerous outreach presentations at scientific meeting on opportunities for NICHD research support for human embryonic stem cell research.

The National Institute on Drug Abuse (NIDA) sponsored a two-day meeting "Stem Cells—Opportunities for Drug Abuse Research" where developmental and general neuroscientists were brought together to pursue the link between drug abuse research to stem cell research and to provide input to NIDA about research directions in this area of endeavor.

The National Institute on Deafness and Other Communication Disorders (NIDCD) is encouraging investigator-initiated projects on high risk/high impact research and administrative supplements to facilitate scientists that would like to pursue preliminary work in stem cell research. NIDCD is sponsoring RFA 02–003 on Cellular Repair Studies of the Auditory and Vestibular Systems. In addition to these research initiatives, the NIDCD Director currently serves as the Chair of the NIH Stem Cell Task Force, a group of high-ranking scientists from a number of NIH Institutes with expertise in the research area of human embryonic stem cells. NIDCD also provides staff support to the activities of the Task Force. The purpose of the Task Force is to identify obstacles to moving the stem cell research agenda forward and to develop strategies to overcoming these challenges.

The National Institute of Dental and Craniofacial Research (NIDCR) encourages and supports research on human embryonic stem cells in studies on oral, dental, and craniofacial development and the development stem cell-based treatments for the repair and regeneration of orofacial structures that have been compromised by congenital disorders, diseases, and injuries. In addition, the Institute co-supports PAR 02–054 Short-Term Courses in Human Embryonic Stem Cell Culture Techniques.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has disseminated NIH policies and procedures to grantees through development of a web-based Investigator's Guide to Human Embryonic Stem Cell Research. In addition to encouraging and supporting investigator-initiated research, NIDDK has a number of RFAs and PAs with research objectives that could encompass the use of human embryonic stem cells. This list includes: PA 01–129 Innovative and Exploratory Research in Digestive Diseases and Nutrition; PA 02–127 Pilot and Feasibility Program Related to the Kidney; PA 01–128 Pilot and Feasibility Program in Hematological Diseases; PA 01–093 NIDDK Expanded Awards for SBIR at NIDDK; and, PA 02–008 Pilot and Feasibility Programs in Diabetes Endocrinology and Metabolism. Also, NIDDK is co-supporting with other NIH institutes research training and infrastructure initiatives targeting the needs of human embryonic stem cell research. These initiatives include: PAR 02–023 Human Embryonic Stem Cell Research Resource Infrastructure Enhancement Awards; PA 02–054 Short-Term Courses in Human Embryonic Stem Cell Culture Techniques; and, PAR 02–069 Career Enhancement Award for Stem Cell Research.

The National Institute of Environmental Health Sciences (NIEHS) actively encourages research on human embryonic stem cells and has established a stem cell research emphasis area to encourage research on organ toxicology with potential for regenerative intervention/prevention technologies. Also, the Institute has initiated working discussions with biotechnology companies to promote their development of programs in human liver stem cell research to address the major public health organ transplantation issues leading to liver failure. In addition, the Institute held a scientific meeting in November 2002 entitled "Stem Cells: Scientific Progress and Future Research Directions" that discussed the potential of human stem cell research both globally and with respect to the environmental health sciences mission of NIEHS. This spring, NIEHS is co-sponsoring the "Frontiers in Human Embryonic Stem Cells Research Training Course and a sequel symposium entitled "Embryonic Cell Biomedicine: The Journey from Mice to Patients" both of which will be held at the University of Pittsburgh.

The National Institute of General Medical Sciences (NIGMS) encourages and supports research on human embryonic stem cells. In fiscal year 2002, NIGMS supported a "Workshop on the Basic Biology of Mammilian Stem Cells" that included key scientists in the field of human embryonic stem cells. Based on this workshop, NIGMS developed the RFA 03–003 Exploratory Center Grants for Human Embryonic Stem Cell Research. In addition, NIGMS issued a Notice 03–002 for Administrative Supplements for Human Embryonic Stem Cell Research and is co-supporting with other NIH institutes the Program Announcement PAR 02–054 Short-Term Courses in Human Embryonic Stem Cell Culture Techniques.

The National Heart, Lung, and Blood Institute (NHLBI) actively encourages and supports research on human embryonic stem cells through a number of Program Announcements, Requests for Proposals, and workshops. NHLBI has invited research applications encompassing human embryonic stem cell research through the following: PA 02–017 Innovative Concepts and Approaches to Developing Functional Tissues and Organs for Heart, Vascular, Lung, and Blood Applications; PA 02–018 Basic Research on Mesenchymal Cell Biology; PA 02–019 Research on Stem Cell Biology and Cell-based Therapies for Heart, Lung, Blood, and Sleep Disorders; and PAR 03–063 NHLBI Competitive Supplements for Human Embryonic Stem Cell Research. Also, the Institute announced NOT 02–009 NHLBI Administrative Supplements for Human Embryonic Stem Cell Research that resulted in the support of several administrative supplements to current grantees to include research on human embryonic stem cells. In addition, NHLBI is co-sponsoring several initiatives with other NIH institutes including: PA 02–025 Plasticity of Human Stem Cells in the Environment of the Nervous System; PAR 02–069 Career Enhancement Award for Stem Cell Research; PAR 02–023 Human Embryonic Stem Cell Research Resource Infrastructure Enhancement Award; and, PA 02–054 Short Term Courses in Human Embryonic Stem Cell Culture Techniques for which NHLBI serves as the coordinator and designated administrative contact for all resulting grants. NHLBI also is sponsoring BAA 03–06 and RFP 03–07 for Somatic Cell Therapy Processing Facilities and Administrative Center that could involve human embryonic stem cells and assist in preparing the cells for clinical research. In addition, the Institute also sponsored an "NHLBI Working Group: Cell-Based Therapies for Regenerative and Reparative Medicine—Vision, Scope, and Directions" in May 2002 that addressed the area of embryonic stem cells, including their future therapeutic potential.

The National Institute of Mental Health (NIMH) disseminates NIH policies and procedures to grantees through development of a web page on NIMH Support for Stem Cell Research. In addition to encouraging investigator-initiated research on human embryonic stem cells, NIMH is co-sponsoring two Program Announcements

with other NIH Institutes: PAR 02–023 Human Embryonic Stem Cell Research Resource Infrastructure Enhancement Award and PA–02–025 Plasticity of Human Stem Cells in the Nervous System. In addition, NIMH sponsored a satellite symposium at the Society for Neuroscience Meeting (November 2002) on "Neuroscience Opportunities in Human Embryonic Stem Cell Research: An International Perspective" and is co-sponsoring an up-coming scientific workshop on "American-Swedish Network for Stem Cell Biology and Neural Repair" currently scheduled for September 2003.

The National Institute of Neurological Disorders and Stroke (NINDS) actively encourages and supports research on human embryonic stem cells. The Institute has developed an NINDS Stem Cell website to update investigators about NIH policy, funding opportunities, upcoming meetings, and other relevant information. In addition, NINDS is sponsoring PAR 02–139 NINDS Cooperative Program in Translational Research and co-supporting with other NIH Institutes PA 02–025 Plasticity of Human Stem Cells in the Environment of the Nervous System and PA 02–054 Short-Term Courses in Human Embryonic Stem Cell Techniques. The Institute has issued several Notices requesting applications for administrative supplements: NOT 02–007, NOT 02–010, NOT 03–002 NINDS Administrative Supplements for Research on Human Stem Cells. These Notices have resulted in support of several administrative supplements that allow current grantees to include and pursue research on human embryonic stems. Also, NINDS co-funded four conferences focused on stem cell research: 8th International Conference on Neural Transplantation and Repair; International Society for Stem Cell Research Meeting; Conference on Stem Cells: Origins, Fate and Functions; and, Gordon Research Conference on Neural Development.

The National Center for Research Resources (NCRR) actively encourages and supports research on human embryonic stem cells. NCRR co-supports PAR 02–023 Human Embryonic Stem Cell Research Resource Infrastructure Enhancement Award and serves as coordinator and designated contact for all the human embryonic stem cell infrastructure grants. In addition, the Institute is supporting a Infrastructure Awardees Meeting in June 2003 that will involve all current infrastructure awardees in an exchange about obstacles and progress to date in developing the respective eligible cells lines for distribution to the scientific community.

The Fogarty International Center (FIC) has been active in conducting outreach with foreign sources of eligible human embryonic stem cell lines. FIC has coordinated the interests of the NIH with the U.S. Department of State and respective U.S. Embassies to establish dialogues with eligible stem cell providers in India, Israel, Sweden, Australia, and South Korea. These efforts have significantly contributed to the five NIH infrastructure awards made to-date to eligible foreign sources.

Question. Please share with us the steps NIH has taken to create a positive environment for human embryonic stem cells and the researchers seeking cures using this promising research tool?

Answer. Over the past 20 months, the NIH has undertaken a number of new initiatives to enable the field of human embryonic stem cell research to move forward:

Train new investigators to culture and work with human embryonic stem cell lines. Currently, there is a limited pool of scientists with the hands-on experience needed to reliably perform experiments using approved human embryonic stem cells. To address this need, the NIH issued a Program Announcement soliciting applications for "Short Term Courses in Human Embryonic Stem Cell Culture Techniques." Five applications were received in October 2002, subsequently reviewed and plans are underway to make awards to all five applications. In addition, to assist mid-career investigators in their efforts to initiate research studies, the NIH issued the Program Announcement. "Career Enhancement Award in Stem Cell Research." These grants will provide salary support as well as some support for other research costs, to allow scientists to join an established research group working with approved human embryonic stem cells for six to twenty-four months.

Provide support to scale up and characterize human embryonic stem cells eligible for Federal funding and increasing accessibility to these lines. In early Winter 2001, many of the 71 independent human embryonic stem cell derivations listed on the NIH Human Embryonic Stem Cell Registry were in the early phases of development and had not been expanded or characterized to the point where they could be readily distributed to the research community. Expanding and characterizing cells derived from human embryos are time- and resource-consuming processes. To help make these cells available to the research community, the NIH issued a Program Announcement, "Human Embryonic Stem Cell Research Resource Infrastructure Enhancement Awards" to provide support to allowable sources of human embryonic stem cells to scale up and distribute cell lines to investigators seeking such lines. The first Infrastructure grant was awarded in April 2002. To date, eight such

awards have been issued. As a consequence of this support the number of cell lines available for widespread distribution has grown from a single cell line in Spring 2002 to eleven cell lines at present, with more anticipated in the near future.

Provide assistance to the research community wishing to use human embryonic stem cell lines in navigating the intellectual property rights (IPR) and licensing agreements or material transfer agreements that needed to be obtained with the owners of the cell lines. The human embryonic stem cells available for Federal funding are owned by private sources, not by the Federal Government. A U.S. patent exists for human embryonic stem cell lines and the techniques used to develop such lines. NIH negotiated a memorandum of understanding with the patent holder (WiCell Research Institute) in September 2001, as well as with several other sources for the use of their cells. While the NIH can only develop such agreements for the NIH intramural research program, the terms of these agreements require the provider to offer the cells under no more stringent terms to other investigators using federal funds to conduct non-commercial research.

Encourage established investigators to initiate research projects involving human embryonic stem cells. In an effort to help established investigators begin experiments using human embryonic stem cells, the NIH announced the availability of Administrative Supplements to existing NIH grants. These supplements are supporting collection of preliminary data that will lead to investigator-initiated research grant applications whose major focus is research using human embryonic stem cells. To date, 42 supplements have been awarded. In addition to these supplements, the NIH is currently supporting 13 investigator-initiated grant awards and additional applications will be considered for funding during the remainder of 2003, and in years ahead. Six NIH Intramural laboratories are currently engaged in research using human embryonic stem cell lines.

Establish an NIH Human Embryonic Stem Cell Characterization Unit. The research community has expressed a need for information on the characteristics of the available cell lines, to allow scientists to select which lines are most suitable for their intended experiments. To address this important need, the NIH intramural program is creating a Stem Cell Characterization Unit. The mission of this unit is to provide reliable and standardized data derived from assays performed on human embryonic stem cell lines available to be shipped to the research community. Performing these assays in a single laboratory will allow a direct side-by-side comparison to be made among the cell lines that are available for shipment, and will facilitate comparison with adult stem cells. These data will arm the scientific community with peer reviewed information about the properties of available lines, so scientists can make an informed choice when ordering one or more of the available cell lines. Data will be posted on a stem cell web site as soon as they have been validated. The assays performed by this Unit will be overseen by a Steering Committee comprised of leading stem cell biologists in both the extramural and NIH Intramural Research community. In a complementary effort, the Mammalian Gene Collection at NIH has established contracts to construct cDNA libraries from several human embryonic stem cell lines, and to perform expressed sequence tag (EST) sample sequencing from these libraries. These libraries will be made available to the research community, and all sequences will be deposited into readily accessible public databases.

Provide support for multidisciplinary teams of investigators to define the properties and potential of human embryonic stem cells. The research community also articulated the need for multidisciplinary, multi-investigator teams of researchers to explore the growth and maintenance, biochemical and molecular properties, and other unique properties of human embryonic stem cells. In response to a June 2002 workshop sponsored by the National Institute of General Medical Sciences, a Request for Applications to support exploratory center grants has been issued. These awards are intended to lead to Research Centers within three years of funding the exploratory center award.

Establish NIH Stem Cell Task Force. In August 2002, the NIH Stem Cell Task Force was established to oversee and coordinate the trans-NIH activities involving human embryonic stem cells, as well as other types of stem cells. Comprised of leading NIH scientists with expertise in stem cell research, the Task Force will continue to monitor the state of this rapidly evolving science, identifying barriers to research progress and addressing the needs of the research community.

Update NIH Stem Cell Web Site. The NIH continues to serve as a resource for stem cell information by hosting a web site. Scientists have access to information on stem cell funding opportunities sponsored by NIH. The web site also includes the NIH Human Embryonic Stem Cell Registry, which lists the eligible cell lines that are available for shipping to researchers.

Host NIH Stem Cell Symposium. The NIH plans to showcase its scientific progress in human embryonic stem cell research by sponsoring a scientific conference at NIH on June 12, 2003. The symposium will feature a morning plenary session with presentations from NIH-supported researchers and an afternoon session will feature workshops and poster sessions.

Question. How many RFAs related to human embryonic stem cell research has your institute sponsored and cosponsored?

Answer. Currently NIH has issued nine Requests for Applications (RFAs) related to human embryonic stem cell research. One RFA invites applications for multiple P20 Exploratory Grants that will support multi investigator teams to conduct research using human embryonic stem cells. Sponsored by the National Institute of General Medical Sciences (NIGMS), this RFA encourages and enables basic biologists with little or no prior hESC experience to work with hESC and establish the utility of hESC as a model system by supporting the development of an institutional infrastructure for research using hESC; encouraging research on the growth and maintenance requirements of hESC; identifying biochemical and molecular markers of hESC; stimulating research that will lead to a better understanding of the unique properties of hESC; and supporting pilot projects that exploit the advantages of hESC as a model system to further the study of fundamental research problems.

Additional RFAs related to hESC research include:

—Innovative Concepts and Approaches to Developing Functional Tissues and Organs for Heart, Vascular, Lung and Blood Applications. These exploratory and developmental grants are sponsored by the National Heart, Lung and Blood Institute (NHLBI).

—Basic and Applied Stem Cell Research for Arthritis and Musculoskeletal Diseases, sponsored by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

—Stem Cells in Development/Repair of Orofacial Structures, sponsored by the National Institute of Dental and Craniofacial Research (NIDCR).

—Basic Research on Mesenchymal Cell Biology, sponsored by the National Institute on Aging (NIA) and National Heart, Lung, and Blood Institute (NHLBI).

—Comprehensive Programs in Beta Cell Biology sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

—Cellular Repair Studies of the Auditory and Vestibular System, National Institute on Deafness and Other Communication Disorders (NIDCD).

—Research on Stem Cell Biology and Cell-Based Therapies for Heart, Lung, Blood, and Sleep Disorders (NHLBI)

—Stem Cell Research for Alcohol related Disorders, National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Question. How many Program Announcements related to human embryonic stem cell research has your institute sponsored or cosponsored?

Answer. The Following Program Announcements related to hESC have been issued by NIH:

—Short Term Courses in Human Embryonic Stem Cell Culture Techniques are supported by 11 NIH Institutes. Five awards will be made in Spring 2003.

The 11 Institutes supporting the short-term courses are:

—National Heart, Lung, and Blood Institute (NHLBI)

—National Cancer Institute (NCI)

—National Center for Research Resources (NCRR)

—National Institute of Allergy and Infectious Diseases (NIAID)

—National Institute of Child Health and Human Development (NICHD)

—National Institute of Dental and Craniofacial Research (NIDCR)

—National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

—National Institute of General Medical Sciences (NIGMS)

—National Institute of Mental Health (NIMH)

—National Institute of Neurological Disorders and Stroke (NINDS)

—National Institute on Aging (NIA)

—Career Development Awards which are sponsored by NIDDK, NIAAA, NINR, NIAID and NHLBI. The announcement was made in March 1, 2002 and expires in June 1, 2005. The purpose of these awards is to provide mid-career investigators with training to use hESC in their research.

—Plasticity of Human Stem Cells in the Nervous System sponsored by NINDS, NIA, NIMH and NHLBI. The purpose of this Program Announcement is to study the fundamental properties of all classes of human stem cells, and to confirm, extend, and compare the behavior of human stem cells that are derived from different sources and ages or exposed to different regimes in vitro and in vivo.

Question. How much funding has been provided for human embryonic stem cell research in each of fiscal years 2001 and 2002?

Answer. In fiscal year 2001, no funding was provided for human embryonic stem cell research and $10.7 million was provided for fiscal year 2002.

Question. Approximately how much funding is your institute planning to provide for human embryonic stem cell research in fiscal year 2003?

Answer. NIH estimates $17.1 million will be provided for human embryonic stem cell research in fiscal year 2003.

Question. Please explain your plans to expand funding within your institutes for human embryonic stem cell research over the next three years?

Answer. Investigator-initiated research is the foundation of grants supported by NIH. To date, NIH is supporting only 13 investigator-initiated research grants using human embryonic stem cells but NIH anticipates a substantial number of applications over the next three years as this field of research matures and more scientists receive stem cell biology training through various training courses, such as the NIH-supported short-term training courses mentioned above or through training offered directly by eligible providers of human embryonic stem cells. Upon completion of the training, it is expected that scientists will address the basic research questions that need to be answered for the field to move forward before being used for human therapies: What are the molecular pathways that govern stem cell differentiation to a specific cell type? How can stem cell growth be regulated? How can stem cells be safely transplanted and how is cell rejection prevented? How long will the stem cell transplant continue to function? Can animal models be developed to test the efficacy of stem cells?

Question. Please identify any administrative or program hurdles that are impeding your institute from maximizing the potential of human embryonic stem cell research in helping your institute achieve its mission?

Answer. Currently, the rate limiting step of hESC research is the lack of well-trained investigators. NIH has taken steps to remedy the situation by funding five short term training courses for up to three years starting in fiscal year 2003. In addition, career enhancement awards to train scientists in the lab culturing techniques and growth methods for hESC are currently being offered for mid-career scientists who are interested in learning to work with hESCs. In addition, NIH is supporting short-term training courses to teach scientists cell culturing techniques. Currently, WiCell, UCSF and ES Cell International are providing additional stem cell training, independent of the NIH-supported short term training courses. NIH has awarded infrastructure grants to providers of hESCs which allows them to grow and culture the federally approved cell lines, making more cells available to the research community. This will enable scientists to gain easier access to the eligible stem cell lines. In June, the NIH is sponsoring a symposium to showcase NIH supported hESC research. The symposium is attracting worldwide interest. NIH believes that these activities will assist in attracting new investigators to the field and alleviate the current shortage of trained investigators.

Question. Several scientists have suggested to the Subcommittee that NIH should create new funding mechanism to support human embryonic stem cell research, given that this is such a new area of science. Are you considering creating a mechanism that requires less preliminary data?

Answer. In an effort to help established investigators begin experiments using human embryonic stem cells, the NIH is issuing Administrative Supplements to existing NIH grants. These supplements are supporting collection of preliminary data that will lead to investigator-initiated research grant applications whose major focus is research using human embryonic stem cells. In addition, NIH is providing other funding mechanisms that are used to support high risk/high impact research as a means for generating preliminary data. Also, the NIH Center for Scientific Review has implemented processes to facilitate the peer review of human embryonic stem cell grant applications. One example is informing scientific review administrators about this new field of research and the preliminary data, which is often part of an application or may be lacking in some grant applications and should not be considered a penalty.

Question. If so, when can we expect this to be announced? If not, how do you plan to spur this field?

Answer. NIH is currently implementing these initiatives. In addition, NIH is undertaking other initiatives to spur this new research field by enabling eligible stem cell providers to scale up cells for shipping, providing easier access of stem cells to researchers, becoming a source of information to the scientific community on stem cell characteristics, and providing a forum for scientists to share their data through a stem cell research symposium.

Question. Most of this type of research takes place at academic health centers, many of which are struggling financially. I also note that you want to re-establish the Biomedical Research Support Grant program to help support academic health centers. Are you requesting funds for that purpose in this budget?

Answer. No funds are requested in fiscal year 2004 to re-establish the Biomedical Research Support Grant (BRSG) program.

Question. For the record, would you provide the Subcommittee with a description of how that program would work, and how much money it would take to adequately support the program.

Answer. No funds are requested in fiscal year 2004 to re-establish the Biomedical Research Support Grant (BRSG) program.

Question. How much does NIH devote to translating basic research into improved health care for the patient?

Answer. An integral component of NIH's mission is to communicate research results both to the lay public and health professionals. NIH works in partnership with many different organizations to communicate scientific results and health information to the medical research community, health care providers, patients, and the general public across the nation. NIH communicates basic research findings through publication in professional journals and by distributing news releases to the science and general media. NIH scientists speak to reporters to explain the significance of the research and put it into the broader context of making progress against disease. Some examples of the translation of research findings from bench-to-bedside that are provided below:

—In 2001, the National Institute of Neurological Disorders and Stroke (NINDS) launched a multi-faceted public education campaign to educate people about how to recognize stroke symptoms and to call 911 to get to a hospital quickly for treatment. Know Stroke: Know the Signs, Act in Time includes: public service advertising for radio, television and print; as well as consumer education materials that include an award-winning 8-minute film, brochures, and posters. Because stroke attacks the brain, a stroke patient often cannot act alone to call 911 and seek medical treatment. Bystanders are integral to acting quickly and getting stroke patients to the hospital.

To date, the campaign materials have derived excellent results. The television PSA garnered more than 87 million viewer impressions and hundreds of thousands of dollars worth of free broadcast time; the radio PSAs received more than 46,000 broadcasts on 272 stations; the airport dioramas were placed in 117 airports, in cities such as Atlanta, Dallas, Denver and Baltimore and received more than 800 million annual impressions; billboard advertising focused in the Southeastern United States, known as the Stroke Belt, averaged more than 800,000 daily impressions for the months they were placed; bus side advertising placed in 10 markets resulted in more than 115,000,000 over the course of three months; a matte service article has generated more than 2 million impressions and about 15,000 requests for Know Stroke brochures, and the consumer education materials developed for the campaign have been requested by thousands of nursing homes, hospitals, senior centers and other organizations. Many of these activities have been done in partnership with the American Stroke Association, a division of the American Heart Association, and the National Stroke Association, the two largest voluntary organizations serving stroke patients and their families.

—The National Diabetes Education Program (NDEP), established in 1995, is a federally-sponsored initiative that involves public and private partners to improve the treatment and outcomes for people with diabetes, to promote early diagnosis, and to prevent the onset of type 2 diabetes. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) and the Division of Diabetes Translation of the Centers for Disease Control and Prevention (CDC) jointly sponsor the program with the participation of over 200 partner organizations. The Program's target audiences include people with diabetes and their families, with special attention to Hispanics/Latinos, African Americans, Asian Americans, Pacific Islanders, and American Indians, people at risk for type 2 diabetes, especially those with prediabetes, health care providers, health care payers, purchasers, and policy makers. The program's main initiatives include the "Control the ABCs of Diabetes" campaign to promote the link between cardiovascular disease and diabetes and the importance of controlling blood glucose, blood pressure and cholesterol, and the "Small Steps, Big Rewards. Prevent type 2 Diabetes" campaign, designed to promote the message that diabetes can be prevented to the 16 million Ameri-

cans with pre-diabetes, a condition that puts them at high risk for developing type 2 diabetes.

—Co-sponsored by NIH and organizations such as the Maternal and Child Health Bureau, the American Academy of Pediatrics, the SIDS Alliance, and the Association of SIDS and Infant Mortality Programs, the "Back to Sleep" National Public Health Education Campaign has resulted in a 50 percent relative decrease in the rate of Sudden Infant Death Syndrome since its launch in 1994. This campaign is directed at mothers and family members of young infants, the professionals responsible for their care, and the public in general.

—The National Eye Health Education Program (NEHEP) has established public and professional education programs to help promote public awareness on how to prevent vision loss. The NEHEP comprises more than 50 public and private organizations, which plan and implement eye health education programs. The NEHEP has created educational kits on glaucoma and diabetic eye disease for health professionals and community leaders. The kits provide information and materials to educate people at high risk about eye health and the need for regular dilated eye exams. The NEHEP also has launched four national public service campaigns. Materials and messages of the campaigns have been tailored to high-risk populations.

—The National Heart, Lung, and Blood Institute supports several long-standing national programs that rely the cooperative efforts of its partners to educate the lay public and health professionals about preventing and treating some of the major chronic diseases of our time. The National High Blood Pressure Education Program (NHBPEP) is a cooperative effort among professional and voluntary health agencies, state health departments, and many community groups interested in hypertension prevention and control. At the core of the program is the NHBPEP Coordinating Committee, composed of representatives from 38 national professional, public, and voluntary health organizations and 7 federal agencies. The program aims to reduce death and disability related to high blood pressure through programs of professional, patient, and public education. The National Cholesterol Education Program (NCEP) was established to raise awareness and understanding about high blood cholesterol as a risk factor for coronary heart disease (CHD) and the benefits of lowering cholesterol levels as a means of preventing CHD. The NCEP Coordinating Committee, with its membership of more than 40 partner organizations representing major medical and health professional associations, voluntary health organizations, community programs, and governmental agencies, helps bring cholesterol information to a wide audience. The National Asthma Education and Prevention Program (NAEPP) was initiated to address the growing problem of asthma in the United States, particularly among children, African Americans, and the elderly. Through its Coordinating Committee, composed of representative from 43 partner organizations from professional medical and health associations, public and voluntary health organizations, and federal agencies, the NAEPP works to raise awareness that asthma is a serious chronic disease, ensure recognition of symptoms, and ensure appropriate diagnosis and effective control of asthma.

CLINICAL RESEARCH

Question. I have a copy of your "road map" for streamlining the process of taking research from the laboratory to the bedside. Is this still in the planning stages or have you implemented it?

Answer. A national effort, led by NIH, to re-engineer the clinical research enterprise is being planned at this time. In the course of developing this key agency priority, the Director, NIH convened a two-day meeting to develop a plan to identify the critical roadblocks and knowledge gaps that constrain rapid advances, and to conceptualize and develop far reaching solutions to build the sophisticated clinical research enterprise of the future.

In January 2003, meeting participants developed a plan to re-engineer the clinical research system over next 10 years. They recommended creation of: (1) National Clinical Research Networks, which would accrue data on clinical outcomes and quality of care at the point of service; provide an infrastructure for rapid initiation of large clinical trials; and inform patients and consumers; (2) a Translational Research Infrastructure which would facilitate the transfer of clinical research findings to the front lines of clinical care-and back; and (3) a Clinical Research Workforce which is diverse, well trained, and capable of collaborating optimally in cross-disciplinary teams.

Since that time, NIH workgroups on translational research, clinical networks and clinical training have been reviewing, consolidating, harmonizing, prioritizing, and

determining the fiscal implications of the myriad recommendations to NIH to emerge from the Clinical Research Roadmap Meeting. Workgroups are actively taking into account key national priorities, scientific opportunities, feasability, timing, and resources. Draft suggestions for implementing the key recommendations for streamlining and updating the clinical research enterprise are being considered by agency leadership. The NIH Director, in collaboration with Institute and Center Directors, will make the final determination of which of the many key directions will be most likely to yield the most substantial benefits to the health of the American people over the course of the next century. Once agreement is reached amongst the NIH Institutes and Centers, operational plans and a timeline will be devised for implementing the new clinical research infrastructure. We look forward to keeping you up to date as these priorities develop.

Question. One of the items in this road map calls for establishing "a natural home within NIH for clinical trials of medical importance." Last year, the Subcommittee encouraged you to establish an Office of Clinical Research to provide a central focus. So we seem to be on the same wave length. Where does that stand?

Answer. NIH views clinical research, which focuses on the causes and consequences of disease in human populations, as the key link in the pathway from basic research to improvements in health. This area of research includes the development of new technologies, mechanisms of human disease, therapeutic interventions, clinical trials, epidemiologic and behavioral studies, and outcomes and health services research. We concur with your strong interest in ensuring the advancement of clinical research. In recent years, the NIH appreciably expanded its clinical research program; for example, by establishing both intramural and extramural clinical research fellowship programs targeted to medical and dental students at the NIH; expanding the resources available for the diverse needs of the clinical research community, including attention to inpatient, outpatient, and critical care clinical research; and investing heavily in Patient-Oriented Research Career Development Awards, Mid-Career Investigator Awards in Patient-Oriented Research, Graduate Training in Clinical Investigation Awards, and Clinical Research Curriculum Awards. In addition, the NIH Loan Repayment Program has been expanded to include health professionals engaged in clinical research funded by non-profit support.

In an unprecedented effort to be responsive to the many and varied research priorities advanced by different stakeholders—practicing physicians, the pharmaceutic and biotechnology industries, researchers, health plans, and patient groups, the NIH Director has convened a series of Roadmap meetings with extramural and intramural scientists and the Institute and Center Directors to explore the scientific challenges in clinical research and the roadblocks to progress. As a result of the recommendations to emerge from these meetings, the NIH is moving forward to re-engineer the clinical research enterprise, and to develop innovative solutions to ensure the promise of a viable 21st century clinical research enterprise.

The development of any new organizational entity at this juncture in the agency's deliberations would stimulate premature closure pertaining to this complex issue affecting all NIH Institutes and Centers. As we continue to develop the NIH clinical research roadmap plan, we look forward to keeping the committee apprised of our progress in implementing these goals as this groundbreaking process continues to unfold.

INCREASED STIPEND LEVELS

In March 2001, NIH announced a commitment to increase stipend levels for Kirschstein research training awards:

The NIH supports higher stipends for NRSA recipients and therefore announces tentative targets of $25,000 for graduate and $45,000 for entry-level postdoctoral stipends. Future budget requests will incorporate 10 to 12 percent stipend increases until these targets are reached. After attainment of these targets, the real value of stipends will be maintained with annual cost-of-living adjustments.

Question. The Administration's fiscal year 2004 budget departs from this commitment. Can you comment on the rationale for this change in policy?

Answer. The change came about through recommendations included in a 2000 National Academy of Sciences report. In fiscal year 2003 the Senate Appropriations Committee and the Conference Committee reports asked NIH to comment on that report. The NIH remains committed to the stipend targets described in our responses on that report. The request for funds to cover a 4 percent increase in fiscal year 2004 will permit the NIH to continue to increase stipends.

APPOINTMENT OF STUDY SECTION MEMBERS

Question. What role should the Administration have in the appointment of NIH study section members?

Answer. NIH operates study section and appoints study section members primarily based on the scientific expertise needed for review of applications assigned to the specific scientific review committees. Technical evaluation and advice regarding the scientific merit of the proposed research requires that the advising panel has the appropriate collective scientific expertise. The Federal Advisory Committee Act, which regulates establishment and operation of NIH study sections, also requires that committees be "balanced" and not "inappropriately influenced by the appointing authority." Trained NIH scientists who develop these committees have the skills and experience to ensure this balance and the presence of the appropriate scientific expertise so as to achieve fair and rigorous reviews. In addition, NIH attempts to ensure diversity (of race and ethnicity, gender, geographic distribution, small and large institutional affiliation, public and private institutional affiliation, academic and small business, etc.) on study sections.

FULLY FUNDED GRANTS

Question. In the Administration's fiscal year 2004 budget request for NIH, 322 new grants are "fully-funded," that is, rather than receiving funding over the 3 or 4-year lifespan of the grants, all funding for these grants would be disbursed in fiscal year 2004. Is my understanding is that this is a pilot or test that is being pushed by the Office of Management and Budget correct?

Answer. Certain grant programs, such as the Academic Research Enhancement Awards (AREA), and the James A. Shannon awards, have always been fully funded. In fiscal year 2004, NIH will increase the number of fully funded grants. NIH will undertake a study to determine the type of grants that can reasonably be fully funded from both the point of financial stewardship and scientific accountability. Other categories of grants may also be proposed for full funding.

Question. If this is to be a test, by what criteria will the success of full funding be judged?

Answer. Factors include ensuring grantee accountability for the use of Federal funds and the availability of funds for new researchers with new ideas.

Question. Currently, as grants are funded over a four-year cycle, there is annual oversight of the research being performed as non-competing continuations are awarded. Will there be less oversight if the grants are fully-funded at one time?

Answer. The overall institutional compliance responsibilities are the same for grants that are fully funded. As noted above, NIH currently has two long-standing award programs that are "fully funded." For example, the Academic Research Enhancement Awards (AREA) program provides for a three -year-award to AREA-eligible institutions. AREA recipients are required to submit an annual progress report to NIH.

Question. As a researcher and research administrator, what is your view of fully-funded grants?

Answer. As a researcher, there are advantages with fully-funded grants in that one can plan a research project with full knowledge and control of the entire amount of the grant award. Thus, one can better plan and manage the budget for personnel, equipment and resources as these are needed to meet the milestones of the project. As a research administrator, full funding could provide additional flexibility in managing future year commitments made to NIH researchers.

Question. Are there upsides or downsides that OMB, the Department or the Congress might not be aware of?

Answer. When determining the type of grants that can reasonably be fully-funded, NIH will consider financial stewardship and scientific accountability, NIH's goal of supporting stable numbers of new grants, impact on research priorities supported through other mechanisms of support, and the impact on new researchers entering the research arena.

TRAINING STIPENDS

Question. In March of 2001, NIH adopted a policy of increasing training stipends by 10 percent a year until appropriate stipend levels are reached. In fiscal year 2002 and fiscal year 2003, the Administration has chosen to ignore NIH's policy and request significantly lower increases for training stipends than are necessary, and the Appropriations Committee has had to take action to ensure that stipends were increased. Here we are in fiscal year 2004, and the Administration has once again un-

derfunded training stipends. What is NIH's view of the need for a 10 percent increase in fiscal year 2004?

Answer. The NIH remains committed to the stipend targets of $25,000 for predoctoral and $45,000 for entry level postdoctoral Kirschstein—NRSA recipients as identified on April 30, 2001. The 10 percent annual increases specified in the 2001 NIH statement would have permitted us to reach the indicated targets by fiscal year 2006. The indicated targets could still be achieved at 4 percent annual increases, albeit not until 2011, by which point they would need to be adjusted to account for changes in the cost-of-living.

Question. What are the numbers of students supported and at what levels?

Answer. Based on distribution of research training positions to various career levels in fiscal year 2001, we estimate that the positions funded in fiscal year 2004 will be filled according to the following table.

REQUESTED FISCAL YEAR 2004 KIRSCHSTEIN—NRSA TRAINEES AND FELLOWS BY LEVEL OF TRAINING

[Full-time training positions]

Career level	Number of positions	Fiscal year 2004 est. stipend levels
Predoctoral	10,046	$19,631
Postdoctoral:		
Years of experience:		
0	1,339	33,629
1	1,163	35,498
2	818	40,494
3	704	42,273
4	842	44,032
5	783	45,803
6	449	47,574
7	1,053	49,588
Total Postdocs	7,151	
Total Full-Time Training Positions	17,197	

Question. Is it your view that stipends are adequate and that we have enough high-quality students in the pipeline?

Answer. As indicated in my previous response, the NIH believes that Kirschstein-NRSA stipends should be adjusted upward to $25,000 and $45,000 for predoctoral students and entry-level postdoctorates, respectively. Stipends are not being adjusted to influence the supply or the quality of students in the pipeline. Based on recent studies, the health-related sciences continue to attract highly motivated students that score very well on national, standardized tests. Stipends are being adjusted upward as recommended by the National Academy of Sciences in recognition of increases in the cost-of-living and because of the high level of education and professional skills involved in biomedical research.

Looking at this budget proposal, I am reminded of those slow motion films of crash tests for cars. My suspicion is that, under the Administration's proposal, we are taking a $27 billion dollar research enterprise and driving it into a brick wall at 60 miles an hour. Fiscal year 2004 is the instant that the car's bumper hits the wall, the crash dummies in the car are just starting to be thrown forward, and perhaps the hood is starting to buckle. I fear that in fiscal year 2005 and beyond we may well "total" the NIH. I didn't double the NIH over the past five years so that we could drive it into a brick wall.

EMBRYONIC STEM CELL RESEARCH

Question. Please discuss how human embryonic stem cell research fits into the mission of the NCI. Has NCI been actively encouraging research on human embryonic stem cell research in order to advance your mission?

Answer. Currently, NCI has not received any research grant applications relating to human embryonic stem cell research. We do believe that we will see basic research applications in the future.

NCI has an extensive commitment to the field of stem cell biology, including both adult and animal embryonic stem cells. This research is important in expanding our fund of knowledge that can be applied to future human embryonic stem cell research. The Institute has publicized to all of our grantees by listserv announcements the current applicable NIH policies and procedures. In fiscal year 2002, NCI spent a total of $95 million in both animal and human adult stem cell research. NCI has also provided vital resources to the research infrastructure through its Mammalian Gene Collection program. This program works with the source of stem cells, such as the program at the University of Wisconsin-Madison, to create public resources for full-length cDNA and genomic libraries of human ES cell lines. In addition, NCI also participates in the NIH task force and implementation team that are facilitating interactions with the scientific communities.

Question. What is NCI doing to provide investigators with the training necessary to maximize the potential of these cells?

Answer. In fiscal year 2002 NCI supported training and education programs for investigators to acquire the skills and techniques necessary to grow and maintain the human embryonic stem cell (hSEC) lines. NCI provided co-funding support to NHLBI for the T15 short courses in hESC culture techniques. The total funding provided was $50,000 per year, divided among the five (5) successful applications. These five awards were made to training programs to help establish the workforce necessary to pursue this research field. These awards will develop, conduct, evaluate, and disseminate short-term courses on laboratory research techniques for human embryonic stem cell lines. The courses will include hands-on experience to improve the knowledge and skills of biomedical researchers to maintain, characterize, and utilize human embryonic stem cells in basic research studies. The courses will improve the skills of biomedical researchers in the maintenance of human embryonic stem cells in culture and their application of this research tool in basic research studies. The long-term objective of the courses is to increase the number of researchers who have both knowledge and skills in the use of human embryonic stem cells in basic research.

REGENERATIVE MEDICINE

Question. Regenerative medicine is an area of research that could be shared by government, academia and industry—a true public-private partnership. Can you outline for the Subcommittee how regenerative medicine fits into your plan for the NIH research agenda?

Answer. Regenerative medicine involves collaboration between several research fields—stem cell biology, biomolecules/biomaterials, and tissue engineering; and involves several scientific disciplines—medicine, biology and bioengineering. NIH places a high priority on supporting regenerative medicine research and is bringing together several working groups to identify research obstacles and address research opportunities for regenerative medicine especially in application to stem cell biology and biomolecules/biomaterials. This process will serve todevelop an NIH roadmap for regenerative medicine with the goal of attracting more scientists to this emerging multidisciplinary field that has the potential of revolutionizing health and quality of life of millions of people.

Recent advances in stem cell research have spurred new interest in the field of regenerative medicine. Before new therapies using human embryonic stem cells (hESC) can proceed to the clinical phase, much basic research must be conducted. There is a need for validating the long-term stability of hESCs in culture and after transplantation, understanding cell cycle control and cell specialization, and evaluating cell-host interactions. In response to these needs, the NIH Stem Cell Task Force is convening a working group with representatives from government, academia and industry to develop recommendations about what steps NIH could take to help improve or develop supporting technologies and research tools in basic research of hESC biology. Topics for discussion would include assessing the needs for supporting supplies, materials, reagents, databases with broad public access; assessing needs, progress, and opportunities for characterization studies, genomic, and proteomic approaches to better define stem cell lines; determining protocols for directed differentiation of stem cells; and recommending needs for enhancing research tools to the Task Force.

SALIVARY DIAGNOSTICS

Early detection offers the best hope for cure for many serious diseases. However, many of the existing ways of diagnosing disease can be difficult, invasive, time-consuming, and expensive, so that by the time people have a test done, it may be al-

ready too late. I understand that saliva as a diagnostic tool is a promising area of research for addressing this issue.

Question. Is there, in the 2004 budget, an investment in this area of research and if there is, how much are you budgeting for saliva research?

Answer. We need to improve methods for detecting and diagnosing disease in the early stages. Unfortunately, there are also many barriers to effective diagnosis. Current methods, like blood tests and imaging technologies, are often uncomfortable, invasive, and expensive. Some diagnostic methods also carry risks themselves. Currently many diagnostic tests do not allow for real time monitoring of the state of health or disease because testing can take days or even weeks to complete.

One of the most promising lines of research for diagnostic testing involves the use of saliva. Like blood and urine, saliva can be used to detect and measure many compounds in the body. Unlike blood and urine, saliva is easy to collect in a physically non-invasive manner, and the mouth is accessible for continuous monitoring. The science of microchip technology is evolving so rapidly that it is possible to envision the day when a microchip could be attached to a patient's tooth and be capable of continuously monitoring not only specific disease conditions but also an individual's overall health status.

NIH is using its resources to make this vision a reality. In fiscal year 2002, NIDCR funded a series of grants to develop strategies to measure and analyze multiple substances in saliva quickly and simultaneously. Working in partnership with colleagues in industry and academia, these grantees are using microchip technology to develop diagnostic tests for a variety of conditions. As these studies are completed, follow-up research will be conducted to determine the efficacy of these new tools.

NIDCR will spend an estimated $9.0 million in fiscal year 2004 on salivary diagnostics research.

Question. Is saliva being used for HIV diagnosis?

Answer. A number of companies have been working on saliva tests to measure antibodies to HIV. However, the sensitivity and specificity is lower than desired, mostly due to the fact that saliva contains low levels of immunoglobulin G. Thus, two companies are using mucosal transudate, the fluid that naturally seeps from the soft tissues of the mouth, as a diagnostic medium. The existing systems are really collection devices. The sample is sent to a laboratory, and the results are obtained after a week or two. Both companies, however, have developed rapid tests that are pending FDA approval for use in the United States. One company received FDA approval on Jan. 31, 2003 for a rapid test that utilizes a finger stick (i.e., blood sample) and provides results in 20 minutes. The same company also has an application before the FDA that uses the same technology with a sample of oral mucosal fluid. FDA approval of the oral mucosal rapid test is expected by the end of 2003.

Question. I hear people talk about the need to develop an "HIV rapid test". Can you explain what that is and are you close to accomplishing that?

Answer. An "HIV rapid test" implies that it can be conducted on site within a very short time frame without the need for specialized equipment or trained laboratory personnel. The NIDCR is working to make this vision a reality. In fiscal year 2002, the Institute funded several grants to develop technologies to measure and analyze multiple substances, including HIV, in saliva. Working in partnership with colleagues in industry, national laboratories and academia, these grantees are focusing their efforts on developing "labs on a chip", miniaturized systems about the size of a credit card for the detection of HIV and other substances. These technologies will allow real-time analysis of a large number of proteins (including antibodies to HIV), nucleic acids (DNA, RNA) and small molecules (e.g., drugs, metabolites) in oral fluids. The development of these technologies would permit fast, highly sensitive and accurate diagnosis of HIV in small amounts of saliva. To date, grantees at the University of Washington and the University of Pennsylvania working in partnership with industry have developed miniaturized prototypes for immunoassays of substances in blood. This technology is currently being adapted for the rapid diagnosis of HIV antibodies in saliva. Once these technologies are developed, they will need to be validated prior to widespread use.

CLINICAL TRIALS RESEARCH IN DENTAL AND ORAL HEALTH

This Committee appreciates the need to support definitive, high-quality clinical trials. We understand that such trials are especially critical in dental and oral health, where large numbers of Americans continue to suffer from oral diseases and disorders.

Question. Are there clinical trials in the area of oral health that need to be conducted?

Answer. Continuing scientific progress in oral health has created opportunities for state-of-the-art clinical trials to determine the effectiveness of new treatment approaches and to broaden our understanding of the link between oral health maintenance and overall health. For example, new clinical trials are underway to assess the effectiveness of periodontal treatment on control of systemic health conditions such as preterm birth. The NIDCR has taken several steps to increase the number of applications and awards for high-quality clinical trials and to enhance the oral health research community's capacity to conduct such trials.

Question. And what plans does NIH have to respond to this need?

Answer. As support for clinical trials in oral health has expanded from about $10.8 million in fiscal year 2000 to nearly $18 million in fiscal year 2002, NIDCR instituted a new process designed to better assist investigators to develop and conduct clinical trials. The Institute has given priority to Phase III clinical trials that are likely to have a major impact on public health policy and/or clinical practices, and that will provide important new information to practitioners and consumers.

NIDCR recently reorganized its extramural programs to delineate more clearly and to focus more prominently on the development and management of clinical trials and recruited additional program staff with expertise in clinical trials. Furthermore, a new, defined path for clinical trial applications has been established, which will assist investigators in developing and conducting trials. NIDCR has given the highest priority to Phase III clinical trials with the potential for high public impact. In addition, the Institute is using a variety of funding mechanisms to strengthen the scientific workforce through expanded training in clinical trial methods. The extramural community has been very positive about these program enhancements, as reflected in the increased number of applications and funding for clinical trials.

SMA RESEARCH BUDGET

Question. What is the budget for SMA basic research for fiscal year 2003 and fiscal year 2004?

Answer. The NIH total estimated funding for Spinal Muscular Atrophy (SMA) is $7,351,000 in fiscal year 2003 and $11,489,000 in fiscal year 2004.

SMA TRANSLATIONAL RESEARCH BUDGET

Question. As a result of promising breakthroughs in basic research along with the severity and incidence of this disease in newborns and infants, NIH has selected SMA as a model for translational research. What is the budget for translational research for SMA in fiscal year 2003 and fiscal year 2004?

Answer. To enhance our current research efforts on SMA, we anticipate awarding a contract for the SMA translational project on or about September 30, 2003. The contract will be awarded for four years, and the research will be conducted as subcontracts. The NINDS intends to fund these research subcontracts at a level of $4.5 million per year, which will support up to ten research subcontracts.

IMPLEMENTATION OF SMA TRANSLATIONAL RESEARCH PROGRAM

Question. Please provide specific details on your plan of action for implementing SMA translational research?

Answer. The NINDS has developed a performance-based contract approach to allow rapid funding of translational research in a milestone-driven process to identify treatments for SMA. The members of the steering committee, selected by the NINDS Director and drawn from academia, industry, the public, and NIH, are in the process of being identified and recruited; they will guide the program and play an integral role throughout the project. During the Summer of 2003, a working group will develop recommendations for a detailed plan for research on promising therapeutic strategies, such as drug development, gene therapy and stem cell therapy, which will address all steps ultimately required to develop an IND-Investigational New Drug-application, the formal procedure usually required before a treatment can be tested in people. The primary contract for the SMA project will provide overall scientific and organizational support. Subcontracts will support individual research projects, which will be highly-targeted and milestone-driven, as is often the case in industry. The steering committee will evaluate progress toward the specified milestones and prepare calls for additional subcontracts to do the next steps along each therapy development pathway, as appropriate. The NINDS intramural program, which has substantial expertise in SMA and other neurogenetic disorders, will play an integral role throughout this effort, and is capable of performing early phase clinical trials when these become appropriate.

OVERSIGHT OF SMA TRANSLATIONAL RESEARCH

Question. Who has been appointed within the NINDS to oversee and execute the SMA translational research project? What mechanisms are in place to review the process of the project on an ongoing basis with NIH leadership and Congress?

Answer. Dr. Jill Heemskerk, an NINDS Program Director, will be the Project Officer for the SMA contract. She will receive advice from the steering committee and other NINDS staff. To allow optimal management and monitoring of research progress by the steering committee, projects will be short-term, goal-directed, and milestone-driven. The steering committee will review research progress at biannual oversight meetings; advise the Contractor in assessment of research milestones; and advise on strategies for overcoming difficulties in research progress.

Institute staff have briefed Dr. Zerhouni extensively about the project and will continue to do so. We have responded to many questions about the project, by letter and phone, from members of Congress, and will continue to keep Congress informed.

TIMELINE AND PLAN FOR SMA TRANSLATIONAL RESEARCH

Question. Please provide a timeline and strategic plan for the implementation of the translational research project and identify any potential roadblocks?

Answer. In December 2002, NINDS published a notice on the "Collaborative Program to Accelerate SMA Therapeutics Development" in the NIH Guide to Grants and Contracts to help develop the statement of work and a request for proposals. A March 23, 2003 notice in Federal Business Opportunities announced that the formal request for proposals will be issued in April, and a similar notice appeared in the NIH Guide on April 8th. We expect to award the primary contract on or about September 30, 2003. Subsequently, calls for proposals for highly-targeted research sub-projects will be issued quickly, and initial research projects should be underway in January or February 2004. Importantly, efforts to establish the steering committee are underway, and a working group should have detailed recommendations for research plans ready by the end of the summer, in time to begin issuing calls for specific research and development projects once the contract is awarded.

With regard to roadblocks, the project depends, of course, on receiving proposals that are sufficiently scientifically meritorious so that we can responsibly fund them. The most serious obstacles to success, however, are scientific. It is important to keep in mind that developing effective treatments for neurogenetic diseases such as SMA is very much on the frontier of medicine. There are very substantial scientific difficulties that must be overcome to develop a treatment for SMA.

PROMOTING AWARENESS OF AND RESEARCH ON SMA

Question. What is NINDS doing to solicit grant applications? What workshops and conferences have been organized this year and next year to increase awareness of SMA and promote research funding opportunities?

Answer. We are using both grant and contract mechanisms to enhance research on SMA. SMA research funding at NINDS increased by 21 percent from fiscal year 2001 to fiscal year 2002; SMA funding grew by more than 500 percent from fiscal year 1998—$945,000—to fiscal year 2002—$5.6 million. This reflects in part the stimulus provided by an NIH workshop and a request for applications—RFA—on SMA and amyotrophic lateral sclerosis—ALS—in Spring 2000. Much of the growth, however, arises from the increased scientific opportunities, and reflects the strength of the traditional investigator-initiated grant process in responding to new avenues for progress. Given the state of the science, we expect grant applications in SMA will continue to increase.

The translational project in SMA that I described is contract-based. In December 2002, NINDS published a notice on the "Collaborative Program to Accelerate SMA Therapeutics Development" in the NIH Guide for Grants and Contracts to help develop the statement of work and Request for Proposals—RFP—for this program. On March 23, 2003 and April 8, 2003 NINDS published notices in Federal Business Opportunities and the NIH Guide, respectively, that the RFP will be released in April.

Other efforts include an NINDS consortium, developed through a solicitation, to screen all FDA approved compounds for activity against neurodegenerative diseases, which included a test specific to SMA. The Institute has a program to rapidly provide supplemental funding for testing candidate treatments that emerge from this, or other efforts, in rodent models. Through a solicitation, the NINDS has also established a high throughput drug screening facility and called for proposals for disease assays, specifically listing SMA among those disease assays being sought. In recent years, we have offered solicitations in several cross-cutting areas that may provide results that are relevant to SMA, focused on areas such as gene therapy for the

nervous system, neural stem cells, and pediatric neurological diseases. The NINDS is also assisting voluntary groups in organizing a scientific conference for Spring 2004 that will, among other goals, help inform biotechnology companies and the pharmaceutical industry about opportunities to develop therapies for SMA.

PROMOTING PROFESSIONAL AND PUBLIC AWARENESS OF SMA

Question. Please identify other NIH institutes and federal agencies that NINDS is working with to promote professional and public awareness of the disease. Please describe the programs that are being developed with a timeline and list of objectives?

Answer. The NINDS has an SMA public information page with links to advocacy organizations, relevant clinical studies, and research literature. The National Library of Medicine also has an information page for SMA with many useful links. In addition, scientific workshops and the variety of research solicitations addressing or referencing SMA, as well as program staff contacts, provide outreach to the professional community. There are a number of voluntary health advocacy groups focused on SMA that undertake extensive activities to inform the public and the research community, as is appropriate to their role, and we have cooperated with these groups in various ways.

STATUS AND COSTS OF CLINICAL TRIALS FOR SMA

Question. What is the status of clinical trials for promising SMA treatments?

Answer. The NINDS is funding a grant to lay the groundwork for clinical trials in SMA by developing a consortium of investigators and by validating appropriate outcome measures. However, at this time we need to emphasize translational research to bring potential treatments to the point where clinical trials are warranted. The NINDS is addressing this need in several ways. The contract-based translational research project for SMA is, of course, an important part of that effort.

Question. What is the estimate cost per trial?

Answer. Estimating the cost of trials and the possibilities of partnering with industry depend on the specific drugs or other therapies that might be tested, so we are not yet at the point scientifically where I can give a specific answer.

Question. For FDA approved drugs, what efforts have been made to partner with the manufacturer of these drugs?

Answer. We also support a consortium of investigators to screen FDA approved drugs for potential use against neurodegenerative diseases, including SMA. We have recently developed a high-throughput drug screening facility as well, and called for proposals to develop disease-specific tests, including those focused on SMA. In addition, the NINDS intramural program will be capable of conducting clinical trials on candidate therapies that emerge from these or other efforts.

ADDITIONAL RESOURCES REQUIRED FOR SMA RESEARCH

Question. What additional resources are necessary to execute the SMA translational research project? What additional resources do you require to increase the focus of SMA research at the NIH?

Answer. We believe we have the resources to execute the SMA translational project at this time. This and all other efforts against SMA depend on the response of the research community to these efforts. The substantial increases in funded research on SMA over the last few years reflect exciting scientific advances, which have brought increases in the scientifically meritorious proposals we receive from investigators, which is very encouraging. The growth also reflects our commitment to addressing this terrible disease.

DUCHENNE MUSCULAR DYSTROPHY—NICHD INVOLVEMENT

Question. Duchenne Muscular Dystrophy is the world's most prevalent, lethal childhood genetic disorder. Only in the past year has the Child Health Institute at NIH had any involvement in this disease. Has the Child Health Institute devoted any specific, significant resources to this disease?

Answer. Since the passage of the MD-CARE Act, the NICHD has partnered with the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) to support the Muscular Dystrophy Cooperative Research Centers and the Developmental Planning Grants for Muscular Dystrophy Research Centers. In addition, over the past five years, NICHD, although it does not have primary responsibility for muscular dystrophy research, has sponsored an active portfolio of grants concerned with the muscular dystrophies, muscle pathophysiology and other neuromuscular dis-

orders. NICHD, along with other NIH Institutes, also has an active role on both the NIH MD Research Task Force and the MD Coordinating Committee.

In addition, through the NICHD-sponsored network of Mental Retardation and Developmental Disabilities Research Centers, resources created under this network have been used to conduct research in some topics related to muscular dystrophy. The National Center for Medical Rehabilitation Research within NICHD has also sponsored research on muscle and neuromuscular disorders including such topics as the effect of stress on dystrophic muscle and the role of strength on child mobility. Finally, the Intramural research program at NICHD has for several years had a research focus on understanding muscle pathophysiology.

DUCHENNE MUSCULAR DYSTROPHY—CONGRESSIONAL PRIORITY

Question. Funding for DMD is approximately ½500 of the NIH budget. This committee has held a hearing on the subject; strong report language has been attached to the Labor/HHS appropriation for three years in a row; a comprehensive muscular dystrophy authorization bill has been signed into law. Is the spending of NIAMS, NINDS, and other institutes consistent with the congressional priority that has been identified for this disease?

Answer. Yes, NIH's funding of muscular dystrophy research is consistent with Congressional priorities. Indeed, from fiscal year 2000 to fiscal year 2002, NIH funding for muscular dystrophy—MD—research has more than doubled. In fiscal year 2000, NIH funding for MD was $12.6 million; NIH funding increased to $21.0 million in fiscal year 2001 and to $27.6 million in fiscal year 2002. Funding for DMD during the same period also increased from $7.0 million in fiscal year 2000 to $12.4 million in fiscal year 2002.

MD-CARE ACT—CENTERS OF EXCELLENCE

Question. The Muscular Dystrophy CARE Act called for the creation of multiple Centers of Excellence, and was signed into law in 2001. This committee on three occasions has said that a minimum of three such Centers should be fully funded. I understand an RFP has finally gone out to organize the Centers, but the only assurance to the scientific community is that two Centers will be funded. Why so few? What funding level is assumed for these Centers?

Answer. The NIH has been actively engaged in implementing the mandates of the MD-CARE Act, including efforts to establish research centers for muscular dystrophy; the Act did not provide for a specific number of Centers. Specifically, in the Fall of 2002, the NIH issued two Requests for Applications—RFAs—in this area. The first solicited applications for up to three awards for Muscular Dystrophy Cooperative Research Centers, and the second solicited applications for up to five awards for Developmental Planning Grants for future centers. During fiscal year 2003, following peer review, we will make grant awards in response to these two RFAs; the number of centers actually funded, up to the specified numbers, will depend on scientific merit. In fiscal year 2004, we plan to re-issue the RFA for Cooperative Research Centers, and expect to fund up to two additional meritorious centers in fiscal year 2005. Subject to the number of applications we receive and the results of scientific peer review, the combined solicitations could result in funding up to a total of five MD cooperative centers. Direct costs for the research centers can be a maximum of $1 million per center per year, for five years.

MD-CARE ACT—CBO ESTIMATES

Question. The MD-CARE Act was scored by CBO two years ago to cost $54 million over four years. Apparently there was a minor increase in funding during the past year, but it is exceptionally difficult to see that this Act is going to be fully funded at the current pace of NIAMS/NINDS activity. What are the prospects for full funding of this Act?

Answer. The Congressional Budget Office—CBO—estimated that implementing the MD-CARE Act—including aspects that are the responsibility of other HHS components—would cost $4 million in fiscal year 2002 and $56 million over the five year period of fiscal years 2002 through 2006. Of this amount, the costs of the NIH activities and of the MD Coordinating Committee, which was established by the Act, were estimated at $2 million in fiscal year 2002, and at $28 million total over the fiscal year 2002 to fiscal year 2006 period. From fiscal year 2001 to fiscal year 2002, NIH actual funding for muscular dystrophy research increased from $21.0 million to $27.6 million, an increase of $6.6 million or 31.4 percent—considerably more than the CBO estimate for fiscal year 2002. Budget estimates for fiscal year 2003 suggest that NIH muscular dystrophy funding would increase another 13.8 percent this fiscal year to an estimated $31.4 million. While this trend of increasing support for

MD research is dependent upon future scientific opportunities and meritorious applications, it should be evident that the NIH is fully committed to implementing the MD-CARE Act, and to defining and advancing the MD research agenda.

MUSCULAR DYSTROPHY—CINRG

Question. Has NIH ever funded translational research into muscular dystrophy—in particular, has NIH ever subsidized the only human clinical trials network (the Cooperative International Neuromuscular Research Group, or CINRG) that is testing pharmacological approaches to delay the progression of this disease?

Answer. The CINRG, with the Children's National Medical Center as its coordinating center, conducts a multicenter clinical trials program to investigate the most promising treatments for DMD and related disorders. NIH currently funds a number of researchers who serve as principal investigators at participating centers for these clinical trials. In addition, NINDS has supported clinical trials on muscular dystrophy through both its intramural and extramural programs, and welcomes proposals for translational and clinical research aimed at delaying the progression of MD and related neuromuscular diseases.

Translational research, by which we mean the process of applying ideas, insights, and discoveries generated through basic scientific inquiry to the treatment or prevention of human disease, is a high priority for the NIH. The emphasis in translational research is squarely on projects focused on the identification and preclinical testing of new therapeutics. The Muscular Dystrophy Cooperative Research Centers will promote side-by-side basic, translational, and clinical research, and will be designed to accelerate the translation of fundamental advances to the clinic. In addition, in July 2002, NINDS initiated a comprehensive program designed to encourage and support translational research for all neurological disorders, complemented by specific initiatives in areas such as drug discovery, gene therapy, and stem cells. Translational research is also an area of focus in the ongoing NIH Roadmap initiative.

MUSCULAR DYSTROPHY—NIH COORDINATION

Question. DMD is untreatable and incurable, and has, throughout history, taken the lives of children in their teenage years. Because of the extraordinary burdens placed on families of children with this disease, most of the benevolence on this affliction goes to subsidize care, not research. While DMD is the#1 genetic child killer, it afflicts one out of 3,500 boys, which is not a threshold high enough to attract private drug money. Hence NIH research is the leading hope for this generation of sufferers. Yet only in the past year has NIH created a muscle biology study group—the only one devoted to the study of the largest organ of the body, out of 110 study groups in all of NIH. Scientific interest in this disease for years had been dampened and frustrated because of this structural flaw. Congress on repeated occasions has suggested that NIH coordinate its activities, and begin to fund this disease commensurate with others—on the basis of prevalence, severity, need, and scientific opportunity. Yet the process of securing adequate funding in this area has been painfully, tortuously slow—testing the limits of congressional patience and willingness to entrust the Institutes alone to designate funding priorities. What assurance can you give that this will change?

Answer. NIH has already taken numerous steps to coordinate its activities with regard to muscular dystrophy. In early 2002, NIH formed the Muscular Dystrophy Research Task Force to help guide efforts to intensify research on muscular dystrophy. The Task Force is made up of physicians, scientists, NIH professional staff, and representatives of voluntary health organizations with a focus on muscular dystrophy. The purpose of the group is to help NIH add new capabilities to the national effort to understand and treat muscular dystrophies, without duplicating existing programs. The Task Force has met twice already—in May 2002 and January 2003.

In September 2002, NINDS, NIAMS, and NICHD jointly issued the request for applications—RFA—"Muscular Dystrophy Cooperative Research Centers—MDCRC," and in November 2002, issued another RFA, "Developmental Planning Grants for Muscular Dystrophy Research Centers." These centers will constitute a cohesive program, the MDCRC Program, operating under guidelines for NIH cooperative agreements. The centers will promote cooperation and coordination of activities and resources across the entire MD research community.

Coordination of MD research and education activities across the entire MD community will also be greatly enhanced by the formation of the Muscular Dystrophy Coordinating Committee—MDCC, as called for in the MD-CARE Act. The MDCC has broad representation from a number of HHS agencies, including the CDC, FDA, and HRSA as well as other government agencies, MD advocacy organizations, and

the public, with an interest in MD research and education. The MDCC is tasked with developing a plan for conducting and supporting research and education on muscular dystrophy through the national research institutes. This plan is to be developed within a year of the establishment of the MDCC and will further enhance the coordination of activities and funding opportunities relevant to MD across NIH.

MUSCULAR DYSTROPHY—NIAMS EFFORTS

Question. What is the NIH doing to ensure an integrated research approach regarding Muscular Dystrophy? What specific corporate processes exist to ensure research synergies and research success? Please provide for the record NIAMS efforts in these regard.

Answer. The NIH has a strong and growing interest in research on muscular dystrophy, and a number of collaborative efforts illustrate this commitment. Over the past few years, several NIH Institutes, including the NIAMS and NINDS, have partnered to support scientific meetings and research initiatives designed to advance the field of muscular dystrophy research. Projects funded as a result of these efforts include work on several forms of the disease, including the Duchenne, facioscapulohumeral, myotonic, and limb-girdle dystrophies. To underscore the importance of expanding and intensifying programs in this field, the NIH has established a Muscular Dystrophy Research Task Force, which includes NIH scientific staff, as well as researchers, clinicians, and patient representatives. This group will help ensure that we pursue all promising opportunities to enhance muscular dystrophy research and training. It will also complement the work of the newly established inter-agency MD Coordinating Committee, which was mandated by the MD-CARE Act. Among other NIH Institutes, the NIAMS has a very active role on both the Research Task Force and the Coordinating Committee.

DUCHENNE MUSCULAR DYSTROPHY—"ROADMAPS"

Question. Are the specific Science and Technology "roadmaps" established for diseases such at Duchenne Muscular Dystrophy? What are the disciplines involved? If so, for the record, please provide these, demonstrating how they integrate multidisciplinary sciences and technology efforts.

Answer. The "Roadmap" Action Plans being developed by Dr. Zerhouni, with input from a broad range of NIH staff and extramural scientific experts, are not disease or discipline specific, but rather take a cross-cutting approach to identify scientific challenges and roadblocks to progress. The "Roadmap" Action Plans will focus on facilitating and accelerating multi-disciplinary aspects of basic, translational, and clinical research. It is likely that several of these areas will be applicable to research on DMD. With regard to muscular dystrophy research overall, the MD Coordinating Committee—MDCC—is tasked with developing a plan for conducting and supporting research and education on muscular dystrophy through the national research institutes. This plan will be developed within a year of the establishment of the MDCC.

MUSCULAR DYSTROPHY—TRANSLATIONAL RESEARCH

Question. Has the NIH ever considered a technology maturity assessment methodology akin to the NASA technology readiness levels or TRLs? Outline for the record the means and process for determination of transition from laboratory science to clinical trial?

Answer. As was mentioned before, translational research—the transition from laboratory science to clinical trial—is the process of applying ideas, insights, and discoveries generated through basic scientific inquiry to the treatment or prevention of human disease. There are rigorous criteria and procedures, which are unique to medical science, for determining when it is appropriate to begin a clinical trial. At the present time, the NIH is in the midst of developing Roadmap Action Plans that will identify opportunities and roadblocks, as well as establish goals, in cross-cutting, multidisciplinary areas such as translational research. We expect that, as these needs are addressed over the next several years, the rate of successful translation of scientific advances into clinical trials will increase.

MD-CARE ACT—IMPLEMENTATION

Question. Outline the specific steps and associated timetime that the Department of Health and Human Services and NIH have been on to fully implement the provisions of the MD-Care Act of 2001. The Congressional Budget office scored the MD Care Act act approximately $54 million for implementation. What are the total resources that NIH has dedicated to implementation of this Act currently reflected in

the fiscal year 2004 President's Budget Submission? Please provide for the record fiscal year 2002 and fiscal year 2003 obligations and expenditures for muscular dystrophy. Please indicate by institute by form of MD, to include, Duchenne, Becker, Limble-Girdle etc.

Answer. In September 2002, NINDS, NIAMS, and NICHD jointly issued two RFAs related to establishing the MD Research Centers provided for in the Act. The RFA for "Muscular Dystrophy Cooperative Research Centers," will establish research centers, each of which will bring together expertise, infrastructure and resources focused on major questions about muscular dystrophy. In November 2002, another solicitation was issued for "Developmental Planning Grants for Muscular Dystrophy Research Centers." These capacity-building grants are targeted to investigators who are not yet ready to compete to establish a muscular dystrophy research center, but would like to do so eventually.

With respect to the MD Coordinating Committee called for in the Act, the public members of the MDCC have been appointed as of April 20, 2003. Nine of the 10 Federal agency members have been designated by the Secretary, HHS, and it has been recommended that the DOD be invited as a member of the MDCC, based on the establishment in fiscal year 2003 of muscular dystrophy research as a project within the DOD's Defense Health Program. Committee members have been contacted about scheduling the first meeting, which is expected to be held in July.

The NIH has also been expanding and intensifying its efforts in MD research. In fiscal year 2002, NIH funding for MD was $27.6 million. Estimated NIH funding for MD research in fiscal year 2003 is $31.4 million and $32.4 million in the President's fiscal year 2004 Budget. The funding by institute follows:

	Fiscal year		
	2002 actual	2003 estimate	2004 estimate
NHLBI	$1,099,000	$1,170,000	$1,200,000
NINDS	9,843,000	12,327,000	12,589,000
NICHD	599,000	600,000	600,000
NIA	1,265,000	1,300,000	1,330,000
NIAMS	11,081,000	12,000,000	12,450,000
NHGRI	2,253,000	2,413,000	2,502,000
NCRR	1,438,000	1,631,000	1,679,000
NIH	27,578,000	31,441,000	32,350,000

The NIH funding for Duchenne MD was $12.4 million in fiscal year 2002, and the estimated funding for fiscal year 2003 is $13.7 million. The reported funding for Duchenne MD in fiscal year 2002, fiscal year 2003, and fiscal year 2004, by institute follows:

	Fiscal year		
	2002 actual	2003 estimate	2004 estimate
NINDS	$4,050,000	$4,373,000	$4,459,000
NIA	1,265,000	1,360,000	1,400,000
NIAMS	4,571,000	5,000,000	5,200,000
NHGRI	2,160,000	2,312,000	2,398,000
NCRR	384,000	430,000	454,000
OD	.....	200,000	.....
NIH	12,430,000	13,675,000	13,911,000

MUSCULAR DYSTROPHY RESEARCH—INFRASTRUCTURE

Question. What are the specific NIH "infrastructure" shortfalls associated with MD research? (ie. RDT&E equipment, laboratory equipment, facilities, facility improvements) Please list any unfunded requirements by institute.

Answer. The NIH's Muscular Dystrophy Research Task Force has identified a number of infrastructure priorities, including the need for multidisciplinary training programs to ensure a steady pipeline of MD researchers; the importance of developing better animal models for MD; the need to enhance bioinformatics and imaging resources; and the need for tissue repositories, DNA samples, and cell lines that can be used by the MD research community. Some of these needs will be addressed

through the Muscular Dystrophy Cooperative Research Centers that NIH is planning to fund over the next few years, while others may require novel partnerships with industry and MD voluntary organizations.

MUSCULAR DYSTROPHY RESEARCH—COOPERATION WITH DOD

Question. Is there any relationship or cooperative research activities with the Department of Defense regarding muscle or myopathies? Between NIAMS and DOD? Or any other institute and DOD?

Answer. NIAMS is aware of the Department of Defense's (DOD) involvement in muscular dystrophy research, as reflected in the fiscal year 2003 DOD Appropriation for the Defense Health Program—Public Law 107–248—in that area. As a result, NIH is recommending that the Secretary of HHS solicit a nomination for a DOD representative to the Muscular Dystrophy Coordinating Committee. This will help to foster the communication and cooperation between DOD and NIH with regard to MD activities.

MYOPATHIES RESEARCH—NIAMS AND NASA

Question. In similar fashion, is there any cooperative RDT&E between NIAMS and NASA on muscle, muscle wasting, or myopathies? Is there any significant relationship to human physiology of flight, especially for long-duration manned space flight? Have NIH institutes made use of any data from NASA regarding muscle preservation with long-duration space flight? Please provide for the record.

Answer. Research cooperation between NIAMS and NASA can be traced at least to the early 1990's, highlighted by a 1990 meeting entitled, "The Effects of Space Travel on the Musculoskeletal System" and a program announcement, which resulted in several grants. In 2000, NASA and a number of NIH institutes—including NIAMS—collaborated on the program announcement, "Earth-Based Research Relevant to the Space Environment," to encourage research applications related to biomedical effects of space flight on humans, including the effects of gravity on the musculoskeletal system. Thus far, the announcement has resulted in the award of at least one NIAMS grant, a project which may provide insights into the use of resistance exercise as a countermeasure to the loss of muscle and bone that occurs during space flight.

DUCHENNE AND BECKER DYSTROPHIES—CLINICAL TRIALS

Question. What is the status of potential clinical trials on Duchenne and Becker dystrophies? Are these efforts fully funded in the fiscal year 2004 President's Budget Submission? Where is this in NIAMS research priorities for fiscal year 2004 and the outyears? Please provide for the record the current status of research on systematic delivery of the dystrophin gene? What are the specific impediments to gene therapy in DMD/Becker? What resources are reflected in the fiscal year 2004 PB for these efforts? Provide a comprehensive list of the "critical technical issues" associated with efficiency of systemic delivery.

Answer. Although much promising research is being done in animal models of muscular dystrophy, significant work remains before the science progresses to the level where major clinical trials in humans are safe and appropriate. Recent progress in developing simple and effective tests that detect more accurately the precise genetic defects in forms of muscular dystrophy may help advance clinical research in this area. By establishing a correct genetic diagnosis, we can identify potential gene replacement strategies, and more accurately estimate risks in families with a history of the disease. In addition, the NINDS has recently funded a pilot clinical trial that will test whether the common antibiotic gentamicin has therapeutic potential for patients with both the Duchenne and limb-girdle forms of muscular dystrophy. This trial may provide new insights that will help shape the course of future clinical studies in this area. Other clinical trials are currently under development.

One potential avenue to pursue, gene therapy, which uses vectors such as viruses to deliver a replacement for the defective gene, is seeing some success in the mouse. Current issues in muscular dystrophy gene therapy include obtaining vectors in significant numbers, effective gene delivery to affected muscles, and prevention of immune reactions to the vector itself. NIH also supports promising work in animal models on the therapeutic properties of muscle stem cells to devise potential new approaches for treatment of MD. Discussions by the NIH Muscular Dystrophy Research Task Force are expected to address these issues.

DUCHENNE AND BECKER DYSTROPHIES—RESEARCH INITIATIVES

Question. What specific research initiatives exist regarding the neuropsychological aspects of DMD/Becker? What resources and institutes are associated with this effort?

Answer. NIH realizes the importance of studying and integrating research on all aspects of a disease—from the physiological to the psychological. NIH has supported research and invites proposals on the neurocognitive and neuropsychological aspects of DMD. More broadly, four NIH Institutes—NINR with NIAMS, NICHD, and NINDS—in May 2002, issued a solicitation on "Increasing Quality of Life in Mobility Disorders." This initiative seeks applications for grants to study the psychosocial aspects of conditions with limited mobility, which could include DMD. These psychological consequences may include anxiety, depression, social isolation, and lowered self-esteem. In February 2003, NINDS also issued a Request for Information for a contract that NINDS is considering to develop a coordinated approach to defining and measuring quality of life in neurological disorders. Patients' social and psychological condition, as well as mental well-being, are among the parameters that may be measured. In addition, NINDS funds very basic studies on the effects of MD-related proteins in brain function. These studies may provide the basis for developing studies on neuropsychological aspects of MD.

The Muscular Dystrophy Coordinating Committee, which is tasked with developing a research and education plan for muscular dystrophy, has broad representation from a number of HHS agencies, such as the CDC, FDA and HRSA, as well as other government agencies such as the Department of Education. This will ensure that all aspects of MD, including the neuropsychological aspects of the disease, are considered in developing the research and education plan.

DUCHENNE AND BECKER DYSTROPHIES—PHARMACOLOGIC APPROACHES

Question. What specific pharmacologic approaches to DMD/Becker are currently being pursued by NIH and NIAMS? What are the resource implications and institutes involved?

Answer. Several years ago, NIAMS-funded scientists successfully used the common antibiotic gentamicin to restore the function of the missing protein dystrophin in mouse models of DMD. More recently, the NINDS has funded a pilot clinical trial that will test whether gentamicin has therapeutic potential for patients with both the Duchenne and limb-girdle forms of muscular dystrophy. This trial may provide new insights that will help shape the course of future clinical studies in this area. The NINDS is also supporting work in mouse models to test the efficacy of the protein biglycan as a potential therapy for Duchenne muscular dystrophy. In addition, early advances involving enzyme inhibitors and growth factors could eventually lead to new pharmacologic treatments.

The NICHD has established a Pediatric Pharmacology Research Unit Network which could prove to be a resource for developing pharmacological approaches in this area.

DUCHENNE AND BECKER DYSTROPHIES—STEROIDS

Question. Has the NIH developed a consensus statement regarding steroids in DMD/Becker? What is the progress here and target dates for such a statement? How is NIAMS participating in this?

Answer. In the spring of 2000, several NIH Institutes, including NIAMS and NINDS, sponsored a scientific workshop on "Therapeutic Approaches for Duchenne Muscular Dystrophy." The goals of this workshop were to address key questions in improving treatments for DMD, and identify areas of needed scientific knowledge, impediments, and critical next steps to promote effective therapies. One of the areas covered in the workshop was the use of steroids in treating DMD patients, specifically the lack of guidelines for use and concerns about side effects in children. Subsequent to this workshop, the American Academy of Neurology—AAN—charged a Practice Parameters Committee with looking at this treatment approach and developing clinical guidelines. The AAN is expected to publish these guidelines in the next few months.

MD CARE ACT—COOPERATIVE RESEARCH CENTERS

Question. The MD Care Act mandated the creation of coordinated research centers in muscular dystrophy research, and suggested a budget of $54 million. Would you verify for the record that the NIH has indeed responded to this by requesting applications for "Muscular Dystrophy Cooperative Research Centers?" Additionally, please detail your goal of funding 2 to 3 centers at the cost of $1 million direct costs

each for 5 years a total of about $15–21 million over 5 years. Is this currently reflected in the fiscal year 2004 President's Budget Submit?

Answer. The CBO estimate of $56 million for implementation of the MD-CARE Act encompasses more than just the creation of research centers; it is an estimate for implementing all aspects of the Act, including those outside of NIH.

As one of the first steps in implementing the Act, NIH issued two requests for applications related to Muscular Dystrophy Research Centers. In September 2002, NIH issued an RFA entitled "Muscular Dystrophy Cooperative Research Centers," to establish research centers, each of which will bring together expertise, infrastructure and resources focused on major questions about muscular dystrophy. In fiscal year 2003, following peer review and selection of applications of the highest merit, NIH will fund up to three centers. In November 2002, NIH issued a second RFA for "Developmental Planning Grants for Muscular Dystrophy Research Centers." These grants, which will be awarded in fiscal year 2003, are targeted to investigators who are not ready to establish a muscular dystrophy research center but would like to do so eventually. Since the President's fiscal year 2004 budget reflects commitments from awards made in fiscal year 2003, the Centers are reflected in the fiscal year 2004 budget.

In fiscal year 2004, we plan to reissue the RFA for Cooperative Research Centers, and expect to fund up to two additional meritorious centers in fiscal year 2005. Direct costs for the research centers can be a maximum of $1 million per center per year, for five years.

MD COOPERATIVE RESEARCH CENTERS—RESOURCE CORES

Question. The committee understands that a second round of competitive awards is anticipated in late 2004, with funding shared between NINDS, NICHD, and NIAMS. Please outline for the record the concept of "Scientific Research Resource Cores." Does this include the Muscular Dystrophy Cooperative Research Centers grant mechanism? Does this initiative ensure that the very best support infrastructures are present and enable the nation-wide muscular dystrophy research community some advantage?

Answer. In fiscal year 2004, we plan to re-issue the RFA for Muscular Dystrophy Cooperative Research Centers, and expect to fund up to two additional centers in fiscal year 2005. At present, NIAMS and NINDS are committed to funding centers of the highest scientific merit through this follow-up initiative. The Scientific Research Resource Cores that will be funded as part of these new centers are expected to serve the national muscular dystrophy research community, in addition to supporting research within the centers. These resource cores will foster multidisciplinary collaborations across departments at a single institution, as well as among investigators at several institutions, through the sharing of novel research tools. Examples of scientific cores include, but are not limited to, tissue and DNA repositories, medical imaging, special animal facilities, and bioinformatics. Investigators at the cooperative research centers are expected to promote the use of the core facilities among researchers within the parent institution and among scientists at other institutions.

MD RESEARCH RESOURCE CORES—ACCESS AND FUNDING

Question. A successful competitive clinical trial network could accept clinical trials for promising therapeutic approaches from muscular dystrophy investigators that are not formally part of one of the two or three funded MDCRCs. Likewise, a successful gene vector or stem cell core facility could produce these critical reagents for laboratories throughout the country. Is the potential increased work load of a successful Scientific Research Resource Cores planned to be funded by the NIH via administrative supplements? Please outline your plans and the funding profiles for record for fiscal year 2004 and the outyears.

Answer. It is expected that an MDCRC will be able not only to accommodate the research ideas and needs of participating scientists, but also to be responsive to other muscular dystrophy research enterprises that may not have direct connections to the center. Cooperation is a key part of the MDCRC's name; the centers are designed to both foster research, and to share knowledge and resources with the muscular dystrophy community at large.

In fiscal year 2004, we plan to reissue the RFA for Cooperative Research Centers, and expect to fund up to two additional meritorious centers in fiscal year 2005. Direct costs for the research centers can be a maximum of $1 million per center per year, for five years. The Scientific Research Resource Cores will be funded as part of these centers. In general, administrative supplements are awarded to already funded researchers in response to identified needs and opportunities within the

scope of the original grant award. Since the center grants have not yet been awarded, any discussion of supplements would be premature.

MD COOPERATIVE RESEARCH CENTERS—FUNDING

Question. It appears that innovative and novel mechanisms that they have put into place for executing the congressionally directed muscular dystrophy cooperative research centers. Please outline for the record the anticipated funding levels and implementation dates for three competitive centers, and evidence of implementation of the innovative Scientific Research Resource Cores via administrative supplements.

Answer. As stated in the recent solicitations for muscular dystrophy cooperative research centers and for developmental planning grants for future centers, the NIH expects to fund up to three research centers and up to five planning grants in fiscal year 2003. In fiscal year 2004, we plan to re-issue the RFA for Muscular Dystrophy Cooperative Research Centers. Direct costs for the research centers can be a maximum of $1 million per center per year, for five years. The Scientific Research Resource Cores, which will be funded as part of these new centers, are expected to serve the national muscular dystrophy research community, in addition to supporting research within the centers.

NIH TUBEROUS SCLEROSIS FUNDING

Question. How much is NIH currently investing in research on tuberous sclerosis complex (TSC)?

Answer. The NIH reported actual funding for TSC research in fiscal year 2002 was $6,121,000. The fiscal year 2003 estimated funding is $6,439,000.

INVESTMENT IN TUBEROUS SCLEROSIS BY INSTITUTES

Question. Since tuberous sclerosis can affect all of the body's organ systems, which institutes are currently supporting this research, and how much is each institute investing?

Answer. The National Cancer Institute—NCI; National Heart, Lung, and Blood Institute—NHLBI; National Institute of Diabetes and Digestive and Kidney Diseases—NIDDK; and National Institute of Neurological Disorders and Stroke—NINDS support TSC research. Funding by Institute is summarized in the table that follows.

	Fiscal year		
	2002 actual	2003 estimate	2004 estimate
NCI	$638,000	$657,000	$677,000
NHLBI	2,140,000	2,279,000	2,336,000
NIDDK	717,000	700,000	700,000
NINDS	2,596,000	2,803,000	2,859,000
OD	30,000	.....	.....
Total	6,121,000	6,439,000	6,572,000

COORDINATION OF TUBEROUS SCLEROSIS RESEARCH

Question. Has there been any attempt to coordinate research on tuberous sclerosis among the institutes involved?

Answer. Yes. The Program Director at NINDS who manages the TSC research portfolio is in regular contact with his counterparts at other Institutes. In addition, program staff from the National Institute of Arthritis and Musculoskeletal and Skin Diseases—NIAMS and NIDDK participated in the September 2002 NINDS-sponsored workshop on TSC research, and these institutes, along with the National Institute of Child Health and Human Development—NICHD, NHLBI, and NCI, are being consulted in the development of the NIH TSC research plan.

TUBEROUS SCLEROSIS RESEARCH PLAN AND REPORT

Question. On September 19–22, 2002, NIH, the Office of Rare Disorders and the Tuberous Sclerosis Alliance sponsored a research conference entitled New Perspectives in Tuberous Sclerosis Complex. In the fiscal year 2003 Senate report the Committee asked to receive a progress report on efforts to develop a research plan. When can we expect to receive this report, and how will it affect future research on tuberous sclerosis?

Answer. In response to a joint resolution of Congress, passed in 2001, NIH is preparing a five-year TSC research plan. Efforts are currently underway, led by NINDS, to craft the recommendations that emerged from the September 2002 conference into a formal research plan. NIH expects to finalize the plan and then submit a report to Congress in June 2003. This plan will help guide the development of NIH initiatives related to TSC and provide a framework that will allow the NIH Institutes and research and advocacy communities to coordinate their efforts to advance TSC research.

PAIN RESEARCH

Question. Chronic pain affects anywhere from 35–110 million individuals per year, and is the most common reason consumers seek health care, accounting for 20–30 percent of doctor visits and 10 percent of prescriptions sold.

The NIH Pain Research Consortium has been in existence since 1996. Can you please provide this Committee with evidence of its activities over the past three years, and its planned activities for fiscal year 2004?

Answer. The NIH Pain Research Consortium was established in 1996 to enhance pain research and promote collaboration among researchers across the many NIH Institutes and Centers that have programs and activities addressing pain. Since its inception, the Consortium has been co-chaired by the Director of the National Institute of Dental and Craniofacial Research (NIDCR) and Director of the National Institute of Neurological Disorders and Stroke (NINDS), and most recently the Director of the National Institute of Nursing Research (NINR) has joined as the third co-chair. The working membership of the Consortium has been comprised of the key representatives of the Institutes, Centers (ICs) and Offices conducting and sponsoring pain research and programs at the NIH. It is designed to promote pain research and to increase awareness in the various NIH ICs in order to stimulate collaborative research initiatives, to coordinate both intramural and extramural research programs, to foster and maintain contact with research and patient communities, and to ensure that the results of NIH-supported pain research are widely communicated.

In its first few years the Consortium:

—Sponsored the symposium "New Directions in Pain Research," which brought together scientists within the mainstream of pain research and exposed them to the work of investigators who do not normally focus on pain. In this way, the symposium brought new ideas, methodologies and techniques to pain researchers, where novel approaches to understanding and treating pain are greatly needed. Summary reports from the meeting appeared in the journals Neuron and Science.

—Sponsored the Symposium "Gender and Pain," which covered subjects such as the differing impact of the sex hormones testosterone and estrogen on pain, brain imaging of nerve pathways involved in the pain response, and efforts to identify genes that affect pain sensitivity. This meeting received a great deal of media attention, and thus information dissemination on the differing responses to pain and current research.

—Established a Pain Research Consortium website on the NIH web that included information on the consortium's mission, its membership, activities being coordinated both intramurally and extramurally, conference proceeding and collaborative funding announcements, among other things.

—Developed a number of multi-institute supported Program Announcements and Requests For Applications in the area of pain research, that were also listed on the website.

—Gave rise on the NIH campus to the formation of the Pain Interest Group, which sponsors seminars, informal discussions and communication via subscription to a list accessible to members of the NIH community.

In addition to these efforts, a number of institute-initiated efforts have been ongoing. Examples include:

—In an effort to enhance the pain consult services within the NIH Clinical Center, the highly successful Pain and Palliative Care Service was established under the direction of a nationally recognized pain clinician, Ann Berger, RN, MD.

—Similarly, the NIDCR-directed Pain Research Clinic accounts for the vast majority of translational pain research done intramurally at NIH and has influenced the field of pain research through training and the scientific productivity of its senior investigators.

—The NIH-FDA Analgesic Drug Development workshop attracted 250 registrants, resulted in a FDA Advisory Committee hearing in July to develop new criteria

for multi-dose studies and claims structure for drugs indicated for Rheumatoid Arthritis and Osteoarthritis, and has catalyzed the first revision of the analgesic drug development process in nearly two decades.

—The NIAMS-led Osteoarthritis Initiative resulted in greater than $50 million in funding, with significant contributions from the pharmaceutical industry, to develop improved clinical trials methods, identification of biomarkers, and an innovative format for future clinical trials for this disease.

More recently, efforts are underway to capitalize and build upon these above activities and to reinvigorate the Consortium. Over the last six years, several changes of leadership in the NIDCR and the NINDS have resulted in a number of changes in individual co-chairs, and, as noted, NINR has joined as the third co-chair. Drs. Lawrence Tabak, Audrey Penn, and Patricia Grady, the current co-chairs of the Consortium, with the support of NIH Director, Dr. Elias Zerhouni, are facilitating the necessary efforts to see the Consortium reach its full potential to catalyze activities both intra- and extramurally in pain research.

To this end, each Institute and Center Director, as well as the central NIH Office Directors, have been contacted and asked to reaffirm their commitment to the pain Consortium as members, and to update their liaisons to the Consortium. In addition, invitations to participate in the Consortium have been extended to NIH's sister agencies, including the Food and Drug Administration, and to pain researchers in the Department of Defense and the Veteran's Administration. An organizational meeting of the revitalized Consortium has been scheduled by the co-chairs to convene on June 10, 2003 to collectively frame the scope and activities of this group for the future, and update the scientific agenda for NIH pain research. Plans for the Consortium, which will address current IC activities as well as those for fiscal year 2004 and beyond, include catalyzing additional multi-institute supported research efforts within both the extramural and intramural programs, including more highly integrated, multi-institute sponsored PAs and RFAs in the area of pain research. The website for the Consortium will also be enhanced to make it an interactive source of more comprehensive information on pain and pain research for its various stakeholders, e.g., pain researchers; patients and patient advocate groups, professional associations, the public, and the media, among others.

Question. According to pain advocacy groups, the NIH has difficulty in accurately accounting for its expenditures in pain and symptom management. Past estimates indicate that the NIH spends less than 2 percent of its total budget on primary pain care research. The American Pain Foundation maintains that in a conversation with the NIH Office of Budget last summer, that office indicated that the NIH spent $124 million on pain-related projects in fiscal year 2000, with an increase to $134.9 million in fiscal year 2001. However, other sources believe that those figures may exaggerate the actual expenditures because they included grant figures where pain was an underlying or secondary focus in the study.

Can you prepare for this Committee an accurate accounting of the NIH's intramural and extramural activity in pain and symptom management research, to include detailed information and accounting on the projects that are primarily addressing pain issues from across the institutes and centers?

Answer. Thirteen of the NIH organizations have reported support for pain-related research, as detailed in the following table and narrative descriptions:

NATIONAL INSTITUTES OF HEALTH; FISCAL YEAR 2002 ACTUAL OBLIGATIONS; PAIN CONDITIONS, CHRONIC

[In millions of dollars]

Participating ICs	Extramural research	Intramural research	Fiscal year total
NCI	10.6	0.4	11.0
NHLBI	10.3	.....	10.3
NIDCR	21.4	5.1	26,5
NINDS	47.7	1.4	49.1
NICHD	4.8	1.1	5.9
NIA	1.8	0.7	2.5
NIAMS	6.6	.....	6.6
NIMH	5.9	.....	5.9
NIDA	22.6	0.4	23.0
NINR	10.9	.....	10.9
NCRR	11.4	.....	11.4
NCCAM	9.0	.....	9.0

NATIONAL INSTITUTES OF HEALTH; FISCAL YEAR 2002 ACTUAL OBLIGATIONS; PAIN CONDITIONS, CHRONIC—Continued

[In millions of dollars]

Participating ICs	Extramural research	Intramural research	Fiscal year total
OD	1.9	.....	1.9
NIH	164.9	9.1	174.0

The National Cancer Institute (NCI)

NCI supports clinical trials on secondary or indirect pain-related research where pain alleviation is a factor in determining patient quality of life during the patient's experimental treatment and care. Pain assessment/pain management research grants investigate how to overcome cultural barriers between providers and patients to better manage cancer related pain. These studies consider gender differences in the effectiveness of similar pain medications. NCI researchers are also developing new methods of pain measurement that are computerized for ease of patient use at the provider site or in the patient's home. Other complementary and alternative medicine pain relief research includes: hypnosis for postoperative breast surgery pain, massage for short-term relief from pain in advanced stage cancer patients, and acupuncture or acupressure for pain relief in advanced pancreatic cancer patients.

Other NCI research examines the biological or molecular basis of pain. Researchers are studying cellular proteins that may be elevated in cancer cells to activate the pain response in humans or animal models. NCI has several ongoing studies on the reduction of therapy-induced pain. These include studies on reversing opioid related constipation as well as determination of initial dosing rates to minimize the pain associated with use of photodynamic therapy for treatment of certain skin cancers. There are several phase II clinical trials underway on therapy induced pain in advanced stage cancers, including a study of radionuclides for metastatic prostate cancer tumors ablation, arsenic trioxide for pain relief of advanced prostate cancer, and radiation as a palliative care measure in advanced lung cancers. NCI is also funding pharmaceutical research on new delivery systems for natural delta–9-tertahydrocannabinol (THC) to alleviate the marked loss of appetite and weight in cancer and AIDS patients.

Emerging evidence from several groups reveals that the capsaicin receptor (a biologic molecule involved in pain sensation) is modulated not only by compounds like capsaicin but also by signaling pathways such as protein kinase C. NCI is actively investigating the regulation of other (vanilloid) receptors by protein kinase C as well as the design of molecules that can manipulate the protein kinase C pathway to obtain useful therapeutic outcomes, such as modulation of pain.

The National Heart, Lung and Blood Institute (NHLBI)

NHLBI supports research on the management of painful episodes associated with sickle cell disease (SCD). Its current portfolio includes a study to ascertain the impact of acute and chronic pain events on health care utilization among adults with SCD, as well as an examination of the relationship between sickle cell pain, mood, and stress in adolescent and adult patients. The NHLBI is also funding a 5-year follow-up of adult patients who participated in a landmark clinical trial that established the usefulness of the drug hydroxyurea in preventing complications of SCD. The goal of the follow-up study is to assess the continuing effectiveness of hydroxyurea in decreasing rates of painful sickle cell episodes and improving quality of life.

The National Institute of Dental and Craniofacial Research (NIDCR)

The history of pain research at NIH began over five decades ago when the NIDCR recognized many Americans' association of dentistry with pain. Since that time, NIDCR, in conjunction with other NIH Institutes, has built a comprehensive portfolio of pain research. Its scientists and grantees have made important contributions to define the basic neurocircuitry of pain, as well as translating this understanding into improved treatments that benefit millions of Americans.

The NIDCR has established relevant research programs initiatives in both its intra- and extra-mural components. NIDCR scientists have long studied oral-facial pain, not only because of its importance in oral disease, but also because it provides an accessible model of pain elsewhere in the body. These investigations have greatly enriched our understanding of the basic mechanisms of pain perception and modulation and have helped delineate the complex pathways and multiple transmitters

that convey pain signals. The NIDCR recognizes that a unique opportunity now exists, with the emergence of genomic, proteomic, and other powerful, information-generating technologies, to define in greater detail the genetic and molecular basis of pain. This basic research will serve as the pipeline for new strategies in pain management, allowing future clinicians to more selectively and efficiently control the pain process.

NIDCR grantees are defining biological factors that might account for differences in pain perception. Novel imaging techniques that track the "mu-opioid" system, have revealed that people vary both in their capacity to produce mu-opioid receptors and in their ability to release the anti-pain chemicals themselves. Researchers found that at matched levels of pain intensity, men and women differ in the degree and direction of the mu-opioid response in distinct areas of the brain. Variability in the mu-opioid system appears to determine the emotional and sensory aspects of a painful experience may also help to explain why some people are more prone to chronic pain conditions or do not benefit from certain anti-pain medications. While the neurocircuitry involved in each of these processes is extraordinarily complex and inadequately understood, these initial imaging studies of pain perception offer an important starting point to further explore human perception and diversity.

In preliminary animal studies, NIDCR scientists have demonstrated a treatment approach that selectively controls the chronic pain associated with tissue damage and recurrent inflammation. This discovery builds upon laboratory studies of the cell-surface protein vanilloid receptor I, known by the unrelated acronym TRPV1. Researchers have isolated a TRPV1-binding compound, which in animal studies selectively eliminates an entire class of pain-sensing neurons from the peripheral nervous system. This compound, known as resiniferatoxin (RTX), killed certain neurons, and blocked inflammatory pain, hyperalgesia, and thermal pain sensation. Importantly, the animals maintained their ability to sense pain and remained well coordinated, an indication that RTX did not affect proprioceptive nerves in the muscles and joints. These NIDCR researchers have yielded in just over a year of work a novel approach to pain management. This finding has important implications for the field of pain research, as well as the potential to impact American public heath. Additional studies are under way that will move RTX and related compounds into human clinical trials.

The National Institute of Neurological Disorders and Stroke (NINDS)

NINDS supports a broad range of research focused on both understanding the causes and mechanisms of pain and on developing effective treatments for pain. Our portfolio includes research on the unique roles in processing and regulating pain that are played by different areas of the nervous system including: the peripheral nervous system, spinal cord, brainstem, and cerebral cortex. The portfolio also includes research aimed at gaining a better understanding of the different neurotransmitter systems involved in mediating pain. The NINDS supports research on a wide variety of pain conditions, including: neuropathic pain, visceral pain, pelvic pain, causalgia, painful peripheral neuropathies, cancer pain, back pain, muscle pain, migraine and other types of headache pain, post-surgical pain, and inflammatory pain. Research on the mechanisms of anesthesia and analgesia is another area funded by NINDS. The NINDS supports a number of clinical studies aimed at testing the effectiveness of different types of treatments (both drug and non-drug) for several pain conditions. For example, one clinical trial is comparing the effectiveness of either a drug or cognitive behavioral therapy for treatment of chronic tension-type headaches. Another clinical study is examining whether behavioral changes (e.g., changes in diet and exercise) can prevent the pain associated with peripheral neuropathy in individuals who have Impaired Glucose Tolerance, a condition of impaired glucose metabolism. Finally, the NINDS supports training programs at both the pre- and post-doctoral level with the goal of giving young scientists and physician-scientists a broad experience in the pharmacological, pathological, and molecular biological methods of pain research.

National Institute of Child Health and Human Development (NICHD)

Chronic pain is a secondary condition in persons with disabilities. Currently funded research on the management of chronic pain explores the efficacy of innovative non-pharmacologic therapies, such as virtual reality analgesia in children with cerebral palsy and burns. Cognitive restructuring, relaxation training and hypnotic analgesia are pain-management approaches being investigated in persons with cerebral palsy, multiple sclerosis, acquired amputation, and spinal cord injury. Research focused on the biomechanics of wheelchair propulsion may reduce shoulder pain and increase the mobility of wheelchair users.

In the area of reproductive health, several investigators are studying pharmacologic treatments for the pelvic pain associated with vulvodynia, endometriosis, dysmenorrhea and hysterectomy. Other pain research examines the effects of epidural analgesia, used commonly to reduce pain in labor. There is evidence that suggests epidural analgesia may also prolong labor, influence the position of the fetus during labor and increase the likelihood of a high-risk cesarean delivery. Pre-term infants are subjected to many painful procedures in the NICU environment. The long-term neurodevelopmental effects of early exposure to pain and the effects of the sedatives and opioid analgesics used to reduce neonatal pain are the focus of other NICHD-supported research.

National Institute on Aging (NIA)

It has been estimated that chronic pain affects approximately half of older adults living at home, and may cause significant disruption of physical, psychosocial, and cognitive function. Management of pain is also of particular concern in older surgical patients, Alzheimer's patients and other patients with diminished cognitive capacity, as well as in end-of-life care. NIA extramural studies include a study of pain management in hip fracture patients and the potential problem of overlooking pain symptoms in patients who experience delirium as well as an investigation of chronic low back pain and its effect on physical, psychosocial, and cognitive function in a group of adults over age 65. Another extramural study is examining the possible effects of a multidisciplinary palliative care consultation on pain management, dypsnea, and anxiety in a group of seriously ill, hospitalized older patients. A new study will research the effect that identifying pre-visit concerns of older adult patients has on improved health status for the primary outcomes of pain and physical function. There is also a study to understand the major determinants of postoperative outcomes and improve functional recovery of elderly surgical patients, including the relationship between improved pain management and improved daily functioning.

NIA has two intramural studies of pain. The first is a study of chronic musculoskeletal pain in hereditary disorders of connective tissue, such as Ehlers-Danlos syndrome and Stickler syndrome, that examines the efficacy of the use of the "Mindfulness-Based Stress Reduction Program" in the relief of chronic pain. The second is an epidemiologic study of the impact of pain and other symptoms of chronic diseases on the daily lives and functioning of older disabled women, which is specifically investigating whether musculoskeletal pain increases the risk for falls and other adverse health outcomes and if the risk can be reduced through the use of analgesic medications.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

The mandate of the NIAMS is broad and diverse, focusing on the whole array of diseases that affect the muscles, joints, bones, and skin. Many of these diseases are chronic, and are also accompanied by significant pain. The origin of pain and effective strategies for pain management are areas of research supported by the NIAMS. The NIAMS pain research portfolio includes a significant number of studies on fibromyalgia, a complex and chronic disorder that is characterized by widespread musculoskeletal pain, fatigue, and multiple tender points. "Tender points" refers to tenderness that occurs in localized areas, particularly in the neck, spine, shoulders, and hips. The NIAMS supported studies related to fibromyalgia and pain include efforts to identify the central factors causing fibromyalgia; research on the changes that occur in the nervous and the hormonal systems in people with fibromyalgia; and a study that is using chronic low back pain as a model for fibromyalgia. Additional research topics include: exploring the roles of sex hormones, stress, and pain in fibromyalgia; work on the employment and health status of women with fibromyalgia; and adaptation to pain and stress in fibromyalgia. Other studies are focusing on rheumatoid arthritis and exploring the value of coping skills training for early rheumatoid arthritis as well as the roles of stress and adaptation to rheumatoid arthritis. Also, the NIAMS has teamed with the NIH Office of Research on Women's Health in funding a new Specialized Center of Research on gender differences in sensitivity to pain.

National Institute of Mental Health (NIMH)

In keeping with the NIMH's mission, over one-half of the pain research NIMH supports is devoted to examining the relationship between pain and mood states. Examples of this work include studying the effects of anxiety on pain perception, and research evaluating depression as a consequence of pain. The NIMH portfolio also includes research on the basic neurophysiology of pain, including both central and peripheral nervous system mechanisms. NIMH also supports studies of the relevant receptors, neurons, neurotransmitters, and neuropeptides implicated in pain.

NIMH-funded work also investigates the efficacy of psychosocial interventions in alleviating and preventing chronic pain. Thirty percent of the pain research funded by NIMH focuses specifically on children and elderly populations.

National Institute on Drug Abuse (NIDA)

The National Institute on Drug Abuse (NIDA) has a comprehensive research portfolio that looks at all aspects of drug abuse and addiction and includes a significant pain and analgesia research program. NIDA's interest in this area stems from the fact that many analgesics also have abuse potential and research on drug abuse and addiction is relevant to pain issues. Thus, NIDA supports the development of treatments for chronic pain, including the use of opioids (e.g. morphine, oxymorphone, fentanyl, codeine) as well as finding alternatives to opioids. Innovative research funded by NIDA includes a device using transcutaneous electrical nerve stimulation (TENS) that was developed through NIDA's Small Business Innovation Research (SBIR) program. TENS stimulates certain nerves in the skin, and this activation inhibits pain. This device is now FDA approved and commercially available. NIDA also supports research on treating some severe forms of pain, such as cancer pain, using transplanted cells from the pituitary gland that produce opioids. Initial work in this area showed that implanting these cells into the spinal cord reduces pain in rats. Researchers are now looking at the use of this technique in monkeys. Another technology using "targeted neurotoxins" is being developed in animal models by several NIDA researchers. This technology is expected to reduce chronic pain by eliminating specific chronic pain fibers in the spinal cord. NIDCR has been examining specific targeted agents acting on ion channels in pain-sensing neurons that have shown potential as a clinical pain treatment. NIDA is partnering with NIDCR in completing toxicology studies on this agent and getting FDA approval for clinical trials in the treatment in cancer patients.

National Institute of Nursing Research (NINR)

Nursing research focuses on ethnically and culturally sensitive interventions for pain prevention, assessment, management, and treatment. Emphases include end-of-life pain management and interventions that help people manage their own pain caused by chronic diseases, such as arthritis. NINR also focuses on the interaction of pain, the immune system, and illness at biological and cognitive levels. NINR supports research on non-pharmacologic interventions to reduce pain, including exercise, music and art therapy, and biofeedback, as well as the improving clinicians' ability to assess pain in those unable to express the level of pain they experience, including infants and cognitively impaired elderly.

Research findings have set a new direction for pain research. For the first time, the influence of gender on pain relief was demonstrated. Study results showed that Kappa opioids, when used for acute pain, are more effective in women than men and have fewer side effects than stronger drugs, such as morphine. The role of hormones on the effectiveness of treatment is currently under study. NINR also conducts research on the importance of pain relief in improving the immune systems response to metastasis following surgery. In an animal model, researchers found that if morphine is provided before and after surgery, the immune system is less depressed, which suggests that pain relief improves resistance to the spread of cancer. Other research findings suggest that exercise helps fibromyalgia patients, who typically have both localized and widespread pain. Patients participating in muscle strengthening achieved the greatest benefit without significant exercise-induced flare-ups in pain.

National Center for Research Resources (NCRR)

NCRR develops and supports critical research technologies and resources that underpin and advance health related research supported by the NIH and other research organizations. Research is carried out through support from the four NCRR divisions: Biomedical Technology, Clinical Research, Comparative Medicine, and Research Infrastructure. The Division of Biomedical Technology supports research resources that enable investigators to do basic research on the biochemistry and physiology of pain. NCRR's Division of Clinical Research supports General Clinical Research Centers where researchers are studying the clinical aspects of pain, including: drug testing and development, gender differences in pain, and pain associated with specific diseases. The Division of Comparative Medicine supports research on pain treatments in animal models, including a mouse model of analgesic regimens for surgery. Finally, the Division of Research Infrastructure supports studies on musculoskeletal pain and pain in children.

National Center for Complementary and Alternative Medicine (NCCAM)

NCCAM supports an extramural pain research portfolio that involves extensive testing of complementary and alternative (CAM) therapies, such as acupuncture, chiropractic medicine, and yoga, to determine their efficacy in preventing and treating pain associated with a variety of conditions and diseases. For example, in a partnership with the National Institute of Arthritis and Musculoskeletal and Skin Diseases, NCCAM is supporting a large clinical trial to determine the efficacy of acupuncture in treating pain and functional limitations imposed by degenerative arthritis of the knee. At the Northwestern Health Sciences University, investigators are comparing chiropractic spinal manipulation, prescription medication, and self-care advice for neck pain, while at Harvard University investigators are evaluating the placebo effect and its role in treating repetitive strain injury. One of NCCAM's major research interests is to study how alternative therapies, primarily botanicals, interact with other medications. At the Fred Hutchinson Cancer Research Center researchers are studying how St. John's wort, a popular herb taken as an antidepressant, interacts with pain relieving opioids in the context of cancer pain therapy. In addition, NCCAM-supported researchers at the Johns Hopkins University Center for Complementary and Alternative Medicine are developing an animal model to study the reduction of cancer pain using herbal medicines that appear to contain anti-inflammatory properties. To help ensure a cadre of clinical investigators in the field of CAM research, including pain research, NCCAM has also awarded a grant to the Palmer Chiropractic University to develop a curriculum on research methodologies for chiropractors.

Office of the Director (OD)

The Office of Research on Women's Health co-funded a total of $1.9 million in pain research projects in the areas of: lower back pain, sex differences that influence pain, cellular mechanisms of neuropathic pain, pain management in temporomandibular disorders, and chronic pain conditions that predominantly affect women.

SCLERODERMA

Question. There is significant vascular and autoimmune component to scleroderma, are there other institutes aside from the NIAMS at the NIH that you would recommend scleroderma researchers pursue to fund experiments aimed at finding a cure? For example, since the leading cause of death in scleroderma patients is through pulmonary hypertension and its effects on heart function, should grants on pulmonary hypertension that encompass issues unique to scleroderma patients be directed to the NHLBI instead of the NIAMS?

Answer. Research on scleroderma is of interest to a number of NIH components. This is one of the strengths of the NIH—that we study diseases from a variety of perspectives. These efforts are complementary, not duplicative. To give an illustration, not an comprehensive list, in the case of scleroderma, the NIAMS is the lead Institute with interests in connective tissue and skin involvement. Other researchers interested in particular aspects of scleroderma include those supported by the National Heart, Lung, and Blood Institute (for example, work on pulmonary fibrosis, pulmonary hypertension, and vascular involvement), the National Institute of Diabetes and Digestive and Kidney Diseases (for example, work on the gastrointestinal tract and kidney function), the National Institute of Allergy and Infectious Diseases (for example, work on autoimmunity), and the NIH Office of Research on Women's Health (because scleroderma affects more women than men). As well, the National Center on Minority Health and Health Disparities also has an interest because of the increased incidence of scleroderma in Native Americans. This means that researchers interested in studying scleroderma should first consider what particular dimension they wish to pursue and contact the relevant Program Director within that Institute. The NIH web site includes links to the individual web sites of each Institute, so this is an effective way to identify the appropriate Program Director for the particular area of interest. I do want to underscore the close collaboration and collegial spirit that we have at the NIH—we team together to sponsor solicitations and to support research in targeted areas as well as jointly sponsor scientific meetings. All of this means that the NIH is able to bring a wealth of experience and complementary interests to a disease like scleroderma.

Question. In your opinion is there sufficient infrastructure (i.e., enough scientists in the field) to support a significant increase in scleroderma funding? Aside from funding more grants specific to scleroderma research, how would the NIH propose increasing interest in the field?

Answer. The issue of infrastructure is of significance to all scientific disciplines and diseases, and the NIH is actively working to address all of the dimensions of

infrastructure. When we look specifically at scleroderma, I am pleased to tell you that this is an area that is the focus of a broad array of research efforts, and I want to cite highlights of several investments. First, the NIAMS made a significant commitment to boosting research on scleroderma when the Institute issued a special solicitation for research applications in fiscal year 2000. This successful solicitation resulted in the funding of ten new research grants totaling more than $2 million. These included both basic and clinical studies, and we were joined by the NIH Office of Research on Women's Health in co-funding two of the grants. The NIAMS also currently funds two Specialized Centers of Research in Scleroderma—one at the University of Texas Health Science Center and one at the University of Tennessee. Specialized Centers of Research (SCORs) increase the transfer of basic research findings into clinical practice by conducting basic and clinical studies under one roof. These SCORs focus only on scleroderma, and they serve as a national resource for researchers studying scleroderma. In addition,, the NIAMS established a national Scleroderma Family Registry and DNA Repository for scleroderma in June 2001 with the goal of identifying susceptibility genes. We believe these investments will provide critically important information on the causes of scleroderma and help us to develop improved treatments. In addition, through Dr. Zerhouni's Roadmap Initiative, infrastructure will be strengthened to facilitate clinical research across the spectrum of clinical diseases.

With regard to increasing interest in the field, scleroderma is an autoimmune disease-a broad category of diseases in which the body's immune system attacks the body's own tissues as if they were foreign invaders, causing significant damage to target organs. The whole field of autoimmunity is currently exploding with activity and newly launched initiatives. Information that we learn from studying one autoimmune disease will provide valuable information for all autoimmune diseases. It is my opinion—and the goal of the NIAMS—that the significant, ongoing work on scleroderma as well as the broad interest in autoimmunity will be of great benefit for affected patients and their families and care givers.

Question. There is strong scientific support for the NIH's "roadmap" meetings with scientists from various disciplines to identify major cross-cutting biomedical challenges that the NIH could help address. How can representatives from the scleroderma community fit into one or several of these meetings to accelerate promising clinical opportunities and better enable new pathways to discovery for scleroderma and other illnesses?

Answer. There is great excitement at the NIH as well as in the voluntary and professional communities about the newly launched NIH Roadmap Initiative and what it will mean to medical research. The NIH is committed to the participation of all of the voluntary and professional groups in this process. Opportunities range from serving as a member on one of the Working Groups that are just being formed, to providing comments through other venues such as public representatives serving on Institute National Advisory Councils or meetings of the NIH Director's Council of Public Representatives. As well, as the Roadmap Initiative moves forward, there will be opportunities to review draft recommendations from the many components of the Initiative as information is posted on the NIH Website and comments sought. I can assure you that NIH is seeking very broad input on this new Initiative, and will welcome the participation and thoughts of members of the scleroderma community as well as all of the other constituent communities.

Question. Approximately what percentage of scleroderma-related grants or requests for funding did the NIH fund last year compared to the last five years?

Answer. NIAMS is the lead Institute at NIH for funding research on scleroderma, and the Institute has undertaken several initiatives over the past 5 years to increase funding in this area. The total NIAMS spending for scleroderma research has grown from $4 million in fiscal year 1998 to over $10 million in fiscal year 2002-an increase of 155 percent. NIH-wide, funding for scleroderma research has grown to a total of $15.1 million in fiscal year 2002.

As mentioned previously, the NIAMS has recently increased efforts to expand the scleroderma portfolio including co-sponsoring a conference on "Emerging Opportunities in Scleroderma Research," which led to the funding of a very successful special solicitation; support for two Specialized Centers of Research on scleroderma to enhance translational research; and support for the development of a national scleroderma family registry and DNA repository, with the overall objective of identifying genes that influence susceptibility to the disease.

VASCULAR DISEASE

Question. There seems to be evidence that vascular diseases—including stroke, high blood pressure, and diabetes—are associated with an increased risk of Alz-

heimer's disease. Some promising initial studies suggest that cholesterol-lowering drugs and changes in diet could reduce that risk. Are you conducting any research along these lines?

Answer. A growing body of evidence suggests that some vascular conditions may be associated with an increased risk of cognitive impairment and/or Alzheimer's disease (AD), and such findings suggest that interventions to treat or prevent these conditions, particularly cholesterol-lowering drugs or dietary changes, could also be used to treat or prevent AD. For example, recent results from a biracial (African American and white) population-based community study in Chicago have suggested that dietary intake of vitamin E can decrease the risk of cognitive impairment and AD and that intake of dietary fats may increase or decrease risk of AD depending on the type of fat, while several epidemiological studies have suggested that individuals who take cholesterol-lowering drugs known as statins may have a reduced risk of cognitive impairment or AD.

The NIA is currently conducting several clinical studies of cholesterol-lowering drugs and dietary modifications for AD treatment or prevention. For example, recent results from the Framingham Heart Study indicate that high blood levels of the amino acid homocysteine, a known risk factor for cardiovascular and cerebrovascular disease, may also be a risk factor for AD. The Alzheimer's Disease Cooperative Study (ADCS) will soon begin a clinical trial to determine whether lowering homocysteine using a combination of vitamins B6 and B12 and folic acid can modify progression of AD over a one-year period. Several other studies using various antioxidants to prevent or treat AD are ongoing. The NIA has also initiated a clinical trial through the ADCS to determine whether the cholesterol-lowering drug simvastatin can slow the progression of AD in people who have mild to moderate disease. Studies using another statin drug, lovastatin, are ongoing or planned.

In addition, the NIA supports a number of basic studies elucidating the mechanisms of interventions that ameliorate both vascular and cognitive dysfunction. These include animal studies on the effects of cholesterol and cholesterol-lowering drugs on cognition. The Institute has provided support to several long-term cardiovascular health studies, including the Framingham Study, the Honolulu Heart Study, and the Cardiovascular Health Study, to explore links between vascular disease and cognitive impairment. We are also working with the National Heart, Lung, and Blood Institute to identify potential areas of collaboration in both epidemiologic studies and clinical trials.

DIABETES AND HYPERTENSION

Question. Within the next 30 years, minorities will make up one-fourth of the elderly population. (16 percent today) Some studies suggest that the two diseases that are most common in minority populations—namely diabetes and hypertension—are associated with an increased risk of Alzheimer's disease. Are you pursuing any research in this area?

Answer. The NIA supports a number of epidemiological studies that are looking for risk and protective factors for AD, including diabetes and cardiovascular disease, in minority populations. For example, the Sacramento Area Latino Study on Aging (SALSA), a study of nearly 1,800 community dwelling Latinos, primarily Mexican Americans aged 60 and above, has recently reported that risk of dementia was nearly 8 times higher in those individuals with both type 2 diabetes mellitus and stroke. In a community-based sample of African Americans in Indianapolis, the investigators found that use of antihypertensive medications was associated with preservation of cognitive function in older adults.

The need to understand the driving factors behind persistent black-white health disparities in cardiovascular disease, cerebrovascular disease, and overall longevity has led to the development of the HANDLS (Healthy Aging in Neighborhoods of Diversity across the Lifespan) study, a community-based research effort focusing on evaluating health disparities in socioeconomically diverse African-Americans and Whites in Baltimore. This multidisciplinary project will assess physical, genetic, demographic, psychosocial, and psychophysiological parameters over a 20-year period. It will also employ novel research tools to improve participation rates and retention. HANDLS researchers will investigate the longitudinal effects of socioeconomic status and race on the development of cerebrovascular disease and cardiovascular disease, as well as changes in psychophysiology, cognitive performance, strength and physical functioning, health services utilization, and nutrition, and their influences on one another and on the development of cardiovascular, cerebrovascular, and cognitive decline.

ALZHEIMER'S DISEASE

Question. In your testimony you talk about the remarkable strides that have been made in understanding Alzheimer's disease. How quickly can we expect some of that new information to be put into the hands of physicians who are treating Alzheimer's patients? Along the same lines, do you feel that there are sufficient clinical researchers trained to translate all of this new knowledge into treatments and better patient care?

Answer. NIA is currently conducting 18 clinical trials, seven of which are large-scale prevention trials. These trials are testing agents such as estrogen, anti-inflammatory drugs, and anti-oxidants for their effects on slowing progress of the disease, delaying AD's onset, or preventing the disease altogether. Other intervention trials are assessing the effects of various compounds on the behavioral symptoms (agitation, aggression, and sleep disorders) of people with AD. In addition, the NIA has a contract in place to facilitate testing of potential new therapeutic compounds in animals. This contract mechanism has now been in place for 8 years and has yielded several potentially promising compounds. So far, two of the drugs that have been tested, AIT–082 and phenserine, have entered human clinical trials.

Although I cannot predict when potential treatments will be available to physicians treating AD patients, I am hopeful that the ability to support clinical trials directed at the multiple molecular targets identified by recent research advances will lead to positive results in the not-too-distant future.

Expanding the numbers of AD-focused clinical researchers has long been a priority of the NIA. Opportunities for clinical research training exist throughout NIA's 29 AD Centers, as well as through the Alzheimer's Disease Cooperative Study. Many of our program project grants have also provided an avenue for training young physician-scientists. An important aspect of each of these mechanisms is the exposure of basic scientists to clinical research; a number of these "clinically-trained" basic scientists are now making important advances in the clinical arena. NIA has also initiated the Markey Training Program, which provides support for supervised research and study for clinically trained professionals who wish to redirect their careers toward research on Alzheimer's disease. In fiscal year 2002, six investigators received Markey Awards.

Efforts are ongoing to find better ways to encourage and facilitate entry of clinicians into research careers (e.g., public/private collaborations, Beeson scholarships for training in geriatric research). Dr. Judy Salerno, NIA Deputy Director, has been leading a major effort, in collaboration with members of the National Advisory Council on Aging, to identify issues that affect the numbers of clinicians entering or remaining in research careers. Related to this effort, a symposium was held in November 2002 in Bethesda entitled "Finding Synergy: Advancing the Development of Physician-Investigators in Aging and Geriatrics" at which experts in the field shared their views of what would be needed to increase the numbers of clinical researchers.

WOMEN'S HEART EDUCATION

Question. I am concerned that heart disease remains the leading cause of death of women in the United States, yet many women do not realize this fact. I hear that you have been working with the fashion industry in your Women's Heart Health Campaign to increase women's knowledge about their No. 1 killer. Please tell the Committee about this initiative.

Answer. The NHLBI launched a new campaign, *The Heart Truth,* last September to convey the message "Heart disease is not just a man's disease—it's the No. 1 killer of women." The Institute unveiled the Red Dress Project as part of the campaign during Mercedes-Benz Fashion Week, February 7–14, 2003, in New York. Fashion Week is a twice-yearly event in which top fashion designers in the United States unveil their new garment lines for the following season. It garners attention from media in the United States and around the world, including editors from most daily newspapers, women's magazine editors/writers, and broadcasters such as Entertainment Tonight and local network affiliates. The Red Dress Project provides a platform to promote the messages of the campaign via the slogan "heart disease doesn't care what you wear." Nineteen red dresses were contributed by leading fashion designers from either vintage or current collections and showcased throughout Fashion Week. A Red Dress Pin, specially designed for *The Heart Truth* campaign by a leading accessory designer, was introduced as the national symbol for women and heart disease.

First Lady Laura Bush wore the Red Dress Pin during her visit to the Red Dress Project display in New York on Valentine's Day. She appeared on *Good Morning America, Today,* and *The Early Show* to promote awareness of women and heart dis-

ease. On February 21, in the Great Hall of the Hubert H. Humphrey Building, U.S. Department of Health and Human Services Secretary Tommy G. Thompson presented The Red Dress Project and designated the third Friday of February as Women's Heart Day. The Red Dress Project is the cover story of the May 2003 issue of *Prevention* magazine and has been featured in *People* magazine and *Newsweek.* A national tour of the Red Dress Project is also being developed, as well as plans to disseminate *The Heart Truth* messages and Red Dress Pin through channels that will reach a diverse population of women.

PARITY

Question. Dr. Insel, as you know there has been a lot of discussion during the last several years concerning the issue of mental health parity—that is, the requirement that health insurance coverage for mental disorders be provided on the same basis as that provided for coverage of so-called physical disorders. What is your view of that?

Answer. As you know, the President has come out in support of parity coverage for mental disorders. Mental disorders are real and devastating illnesses. They account for a large proportion of the disability caused by all medical illnesses. Research supported by NIMH shows that the increase in cost to provide parity coverage for mental disorders can be limited, but not treating them would be very costly.

MEN AND DEPRESSION PROGRAM

Question. I note that NIMH has recently launched—with the help of the Surgeon General of the United States—a major public campaign focused on men and depression. Can you tell me why you've done that?

Answer. Depression is a treatable medical disorder that causes terrible suffering for its victims and is the cause of many of the Nation's 30,000 suicides each year. A major obstacle to getting people into treatment, however, is the stigma that accompanies admitting that you're depressed and that you need help—and this is especially true of men, including men who have suffered trauma. To help men recognize the signs of depression and to guide them toward more information and sources of assistance, the NIMH recently launched the "Real Men/Real Depression" public education campaign.

Question. Isn't it true that far more women than men develop depression?

Answer. Yes, more women than men are diagnosed with depression, but men do have depression and are less likely to seek treatment. One indication of the importance of this campaign is that four times as many men as women die by suicide. Figures from the Centers for Disease Control and Prevention and the 2000 census show that more than 70 percent of all suicide victims are white males.

Question. What do you hope to accomplish with this?

Answer. The NIMH estimates that more than 6 million American men suffer from depression every year. We are trying to overcome the barriers that prevent these men from seeking help, and we are hoping to reduce the number of suicides in this country as a result of this effort. We already appear to be having success, based on the many thousands of e-mails and letters asking for help or more information that we have received to date—not only from depressed men, but from their friends, their family members, their co-workers, and others who care about them.

BUDGET REQUEST

Question. For fiscal year 2004, the President is proposing $1.382 billion for scientific and clinical research at NIMH. This is $41 million over the fiscal year 2003 appropriation of $1.341 billion—a 3 percent increase. This is barely enough to cover inflation and below expected increases in the cost of conducting clinical research. The Subcommittee is concerned that this funding request could prevent NIMH from sustaining the ongoing multi-year research grants that have been initiated over the past 2–3 years. What would be the impact of holding increases at NIMH to 3 percent this year? Would NIMH be able to continue ongoing, multi-year research programs such as the plan on mood disorders and bipolar disorder? Can you provide us with an estimate of the number of qualified grant proposals that you would expect to be unable to fund if NIMH's budget is held to a 3 percent increase in fiscal year 2004?

Answer. Under the proposed 3 percent increase for NIMH's fiscal year 2004 budget, the Institute will honor its commitments to ongoing grants that have been funded over the past several years. The proposed budget provides funds to proceed on schedule in addressing the scientific priorities identified in The Strategic Plan for Mood Disorders Research. In fiscal year 2004, the NIMH estimates receiving a total

of 2,535 applications for research project grants (RPGs). At the fiscal year 2004 President's Budget level, NIMH would fund an estimated 636 of these applications while the remaining 1,899 RPGs would be unfunded. This is a success rate of 25 percent and is consistent with NIMH success rates over the last few years

RESEARCH

Question. While steady funding increases have been achieved in the area of severe mental illness research, research on these illnesses remains underfunded, given the severe burden that these diseases present to the nation's public health. A 1996 independent study by the World Bank and World Health Organization (DALY: Disability Adjusted Life Years) found that four of the top ten causes of disability worldwide are severe mental illnesses: major depression, bipolar disorder, schizophrenia, and obsessive-compulsive disorder. But using the most recent estimates from NIH, research on mental illness lags far behind other diseases relative to public health costs, lost productivity, disability, etc.

What efforts are underway at NIMH to focus greater attention and resources on promising research at the basic, clinical, and services levels on severe mental illness such as schizophrenia, bipolar disorder and major depression?

Answer. NIMH maintains energetic communications, public liaison/outreach, and public education programs, all of which are designed to draw attention to the opportunities and payoff of research on mental and behavioral disorders. The Institute's award-winning home page presents a wealth of information, (www.nimh.nih.gov) about mental disorders and recent progress in NIMH sponsored research. The page receives approximately 10 million hits per month from the public as well as members of the scientific and clinical communities. In April, NIMH launched a new mass media campaign, Real Men. Real Depression., which is focused on the leading cause of disability adjusted life years in the United States. The campaign features real men—that is, not actors—describing in everyday language what it felt like for them to be depressed. They talk about their confusion and concern for their ability to care for their families, about their jobs, about plans and hopes that are so easily shattered by depression. They talk about the difficulty of acknowledging that they were depressed and the struggle to force themselves to get help—help that is available largely because of NIMH-sponsored research.

TREATMENTS

Question. In the last decade, many new treatments and services have been developed and proven for severe mental illnesses such as schizophrenia. Yet most individuals with these illnesses receive extremely poor treatment. What efforts are underway (or ongoing) to ensure that the improved treatment interventions being developed now will be effectively disseminated to providers and made available to the people who so desperately need these treatments?

Answer. NIMH supports research on testing the best methods for dissemination of knowledge, whether in the form of evidence-based reports, algorithms, or guidelines. In addition to building a stronger base for understanding what are the best methods for sharing information, we also are engaged in research that seeks to determine how information is translated into sustained practice, or more simply put, how to get individuals, practitioners, and health care systems to adopt effective research-based practices. Examples of some of the grants we currently fund include studies that examine the use of depression guidelines in primary care settings, and the use of practice guidelines by physicians to improve care for hospitalized youth with aggression and impulsivity. Another project examines the use of the internet in educating families on care issues related to schizophrenia, while another applies technology for physicians' use with decision making in prescribing medications in community mental health clinics. Examples of program activities that occurred during 2002 include:

—Two workshops on diffusion of evidence based practices in state mental health systems

—Workshop on special issues in disseminating research findings for child and adolescent mental health

—Initiation of new grants mechanisms that increase the capability of providing centers to evaluate the delivery of their interventions and improve their practices; and expedited submission, review and funding of applications where evaluation of changes being made in a delivery system requires time sensitive research.

Question. How is NIMH collaborating with SAMHSA and the Center for Mental Health Services (CMHS) on these efforts?

Answer. The Science to Service Initiative that involves SAMHSA Centers and NIH institutes (NIMH, NIDA, and NIAAA) has as one of its goals the exchange of evidence-based practices that can be implemented by SAMHSA in natural settings, and then further researched by NIH as treatment and services questions arise from the practice field. NIMH is the principal source of support for mental health services research in the DHHS. In the past 22 months, we have been able to increase the number of services research applications by 45 percent. We are providing technical assistance to former SAMHSA grantees through workshops and individual consultations and working closely with CMHS staff members. Through co-sponsored activities we are working together to build the capacity of state mental health agencies and other "natural treatment settings" to conduct research on the treatment they are providing, to evaluate its effectiveness and to examine factors that will increase readiness for adoption of research-based care.

SERVICES RESEARCH

Question. Administration is returning agencies to their core mission, meaning that NIMH, rather than the Substance Abuse and Mental Health Services Administration, will be conducting services research on mental health issues.

To what degree is NIMH prepared to assume greater responsibility with respect to services research?

Answer. NIMH is the principal source of support for mental health services research in the DHHS. In the past 22 months, we have been able to increase the number of services research applications by 45 percent. We are providing technical assistance to former SAMHSA grantees through workshops and individual consultations and working closely with CMHS staff members. The Science to Service Initiative that involves SAMHSA Centers and NIH institutes (NIMH, NIDA, and NIAAA) has as one of its goals the exchange of evidence-based practices that can be implemented by SAMHSA in natural settings, and then further researched by NIH as treatment and services questions arise from the practice field.

Question. People with mental illnesses often have conditions besides a mental health diagnosis. To reflect the real world in which mental health services are delivered, how will NIMH services research address people with multiple diagnosis?

Answer. To insure rigor and maximize the possibly of detecting a treatment effect, randomized, controlled clinical trials—the traditional "gold standard" for medical research—have excluded anyone with a comorbid mental disorder, substance use disorder, general medical illness or other conditions ranging from pregnancy to active suicidality. Thus, the typical clinical trial for an antidepressant would be conducted with a relatively small, highly homogenous number of outpatients or, less frequently, inpatients, usually in an academic health center. The major outcome criterion would be a decrement on a behavioral rating scale such as the Hamilton Depression Scale.

In real life, of course, the patient who typically appears in a psychiatrist's office is quite unlike the patient enrolled in the traditional clinical trial. Accordingly, while the NIMH will continue to fund the traditional form of clinical trial, the Institute's researchers also are adapting to the changing nature of treatments, patients, and the health care environment. In order to help clinicians provide optimal care to patients, research today also involves trials with larger sample sizes and with fewer exclusion criteria; trials are being conducted not only in academic clinics but also in more real world settings including managed care settings; and outcomes are assessed not only on the basis of symptom reduction but also on measures of functional rehabilitation, the end result that is of greatest interest to families and patients as well as employers and others who pay for treatment. This new type of trial—often called an "effectiveness" trial—need not give up any of the traditional and indispensable emphasis on rigor. In trials of both pharmacotherapies and psychotherapies, the information sought should be geared toward helping clinical decision-making in real world settings and should demonstrate compelling types of functional outcomes. From a methodological perspective, new analytic techniques are being developed that allow clinical investigators and services researchers to move away from linear patterns and account for the complex interactions that occur in the real world.

Question. Research at NIH focuses on randomized, clinical trials, despite the fact that many other proven research methods are more conducive to services research (such as multi-site research or analysis of nationally representative data sets such as the Census Bureau's Current Population Survey or the National Health Interview Survey). To what degree will NIMH utilize these other methods?

Answer. NIMH supports a wide array of research designs and methods, not just randomized clinical trials. Researchers have the freedom to use the best techniques

available to address the questions they are asking. This might involve using statistics to analyze large national data sets as in studies of risk factors for depression in children, or the use of interviews and qualitative techniques for research questions that require more context to understand. Other studies require control of variables to get at causation; thus randomized clinical trials are appropriate. Epidemiologic studies are also conducted in which surveys are the basic tools used. In summary, no one approach is used-the research question asked dictates the method to be used.

SCHIZOPHRENIA

Question. Schizophrenia is the most devastating mental illness, affecting approximately 2.2 million American adults, or 1.1 percent of the population age 18 and older. Scientists still do not know the specific causes of schizophrenia; like many other medical illnesses such as cancer or diabetes, schizophrenia seems to be caused by a combination of problems including genetic vulnerability and environmental factors that occur during a person's development. While newer treatments for schizophrenia such as atypical anti-psychotic medications are proving effective, these treatments are largely palliative and help patients live with, rather than recover, from the illness.

Given the enormous public health burden associated with schizophrenia and the demand for new treatments, what is NIMH doing to assure that the research base studying schizophrenia is strengthened and expanded?

Answer. Recognizing that schizophrenia is among the most serious public health problems facing Americans, the NIMH has increased the proportion of it's budget devoted to this and other related neurodevelopmental disorders from 16 percent to 23 percent in the last five years. Reflecting the higher priority afforded this severe illness within NIMH, new initiatives have been launched that balance the need to focus on discovering the fundamental cause of the disease so a cure might be possible, with the need to improve treatments for patients who are suffering today.

Efforts to understand the etiology of schizophrenia and other devastating mental illnesses are grounded in the neurosciences. For example, the NIMH Human Genetics Initiative is in the process of collecting biological materials on over 17,000 individuals to create a national scientific resource of DNA for broad use by investigators in the scientific community. Such samples help to identify risk genes associated with schizophrenia and shed light on the mechanisms malfunctioning in the brain. The Research Centers of Excellence (Silvio Conte Centers for the Neuroscience of Mental Disorders) have been established to develop and follow new leads generated by genetic and other basic studies in order to clarify abnormalities in brain functioning associated with major psychiatric illnesses. Over half of these Centers focus on schizophrenia, including two new centers (Mt Sinai, in New York City, and the University of North Carolina, Chapel Hill) that have been funded in the last fiscal year.

BIOPLOAR DISORDER

Question. Bipolar disorder, or manic depression, is a serious brain disorder that causes extreme shifts in mood, energy and functioning. It affects 2.3 million adult Americans, or 1.2 percent of the population. Currently, there is no cure for bipolar disorder. While it can be a highly treatable and manageable illness, most of the approved treatments are indications associated with medications that were developed for other illnesses (anti-convulsants for epilepsy and anti-depressants). In 1997, Congress requested NIMH to undertake a national research plan on bipolar disorder. This request resulted in the current research plan on mood disorders at NIMH. Can you please update the Subcommittee on the mood disorders research plan and what NIMH is learning about the causes and new treatments for bipolar disorder?

Answer. NIMH completed the Strategic Plan for Mood Disorders last year and is now in the process of implementing the highest priority recommendations for new research on the nature, course, treatment, and prevention of these disorders. In addition, we are systematically monitoring and evaluating the ongoing research activities in each of the Divisions from neuroscience to services, to ensure movement toward our goals.

In 1998 NIMH initiated funding of the STEP-BD program (Systematic Treatment Enhancement Program for Bipolar Disorder), a multisite study of bipolar disorder that is now following nearly 3,000 individuals receiving care for bipolar disorder in 18 centers across the United States. The budget for STEP-BD is approximately $25,000,000. This study is providing unique information on the course of bipolar disorder and on targets for treatment. We have learned, for example, that even under

optimized treatment conditions about 5 percent of people with bipolar disorder will experience a relapse during the course of a year. Significantly, and counter to expectations, 80 percent of these relapses are depression, not mania, thus highlighting the need for safe and effective treatments for bipolar depression. Studies have been initiated to explore the value of rational strategies of combination treatment targeting bipolar depression. One of the benefits of large studies, such as STEP-BD is they provide training grounds and engender interest for new studies in bipolar illness. In fiscal year 2003 NIMH will be funding the first center specifically targeting interventions in bipolar illness in adolescents and adults-this new center is established at one of the primary sites of the STEP-BD study.

With an increased awareness that bipolar disorder also affects children and adolescents, NIMH has recently funded two multisite trials to study the benefits of medications for youths with this disorder.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

PARKINSON'S

Question. Dr. Zerhouni, I appreciate that you have focused some of your attention on Parkinson's disease during your first year as director and that you and your staff have developed a "matrix" that outlines future NIH-funded research on Parkinson's. This matrix follows the release in 2000 of the NIH Parkinson's Disease Research Agenda. As you know, I have been concerned that funding for PD research during the past few years has increased at a rate below the overall percentage increase for NIH, despite the professional judgment estimates included in the Research Agenda. Please explain what the NIH is doing to fully implement the Research Agenda as well as the matrix.

In addition, the President's proposed budget for fiscal year 2004 includes $35 million for "Roadmap Funding." The Budget describes its purpose "as an additional effort to accelerate fundamental discovery and translation of that new knowledge into preventive and therapeutic strategies." Will you be focusing on any particular diseases when you implement the Roadmap, and will Parkinson's disease be one of the diseases you will choose?

Answer. With regard to funding, NIH funding for Parkinson's disease research has been growing much more rapidly than the growth of the overall NIH budget, which of course has been very significant. During the first four years of the doubling effort—fiscal years 1999 through 2002—actual NIH funding for Parkinson's disease research rose approximately 92 percent, while the overall NIH budget rose by a very generous 72 percent. To fully appreciate this increase, it is critical to recognize that in fiscal year 1998—the "base" year of the doubling—NIH had just increased its funding of Parkinson's disease research by 23 percent over fiscal year 1997, while the overall NIH budget increased only 7.2 percent in that time frame.

More importantly, the NIH Parkinson's Disease Research Agenda and its updates encompass every research area critical to Parkinson's disease—genetics, environmental factors, cell death and survival, pharmacological treatments, deep brain stimulation, gene therapy, stem cell research, and the non-motor effects of Parkinson's—and the NIH is addressing every scientific aspect of that Agenda. This includes hundreds of research grants and contracts, at all levels of research, from basic through translational to clinical, including major clinical trials. We are following all plausible strategies to develop therapies, including drugs, surgery and cell transplantation. We have also held several scientific meetings since the original Agenda was developed to adjust to the changing scientific landscape, and to make sure that all scientific opportunities are pursued. This includes a "summit" of Parkinson's disease researchers that I convened in July 2002 to identify roadblocks that might be impeding progress. The Summit was very successful in identifying roadblocks, and NIH staff has drafted a matrix of short-to-long term, and low-to-high risk action items designed to target these issues. NIH is actively addressing these action items, both through enhanced support of individual Institute and Center efforts, and through improved coordination and collaboration with the research and voluntary Parkinson's communities.

The Roadmap initiatives, being developed with input from a broad range of NIH staff and extramural scientific experts, are not disease or discipline specific, but rather take a cross-cutting approach to identify scientific challenges and roadblocks to progress. Driven by the enormous convergence in fundamental research approaches and technologies across diseases, organs and biological systems, the Roadmap will focus on facilitating and accelerating multi-disciplinary aspects of basic, translational, and clinical research. Roadmap initiatives will exploit new unprece-

dented opportunities and technologies that will accelerate progress in disease areas across the 27 Institutes and Centers of the NIH. The exact nature of the progress will differ with each disease depending on our current knowledge of the disorder. Some diseases, which are in need of further basic research, will be aided by initiatives supporting portions of the Roadmap such as New Pathways to Discovery. Other diseases will benefit from Roadmap efforts aimed at optimal translation of discoveries into clinical reality, such as Clinical Trial Networks.

NATIONAL LIBRARY OF MEDICINE

Question. The NLM and its Center for Biotechnology Information have made a major contribution to the fight against disease. To maximize this contribution, this committee has supported the design of a new facility. How is that going, and are you ready to initiate construction if funds are made available?

Answer. The design of the National Center for Biotechnology Information is expected to be complete by August-September 2003 at which time the NIH, in consultation with the HHS Office of Facility Management and Policy, will develop a plan for scheduling and financing this project while considering other demands and priorities.

QUESTIONS SUBMITTED BY SENATOR PETE V. DOMENICI

MENTAL ILLNESS RESEARCH

Question. Dr. Zerhouni, can you please update the Subcommittee on efforts underway at NIH and NIMH to focus greater attention and resources on promising research at the basic, clinical, and services levels on severe mental illness such as schizophrenia, bipolar disorder and major depression to ensure that advances rapidly translate into better treatment for individuals living with these illnesses?

Answer. At NIMH extensive efforts are underway to translate basic science findings (from genetics, structural and functional brain imaging, analysis of human post-mortem brain specimens, etc.) to an enhanced understanding of the causes (etiology and pathophysiology) of the major mental disorders. In the past few years significant progress has been made in identifying risk genes, refining disease phenotypes (characterizing more homogeneous subpopulations of patients), and implicating particular brain molecules, cells, circuits and structures as key players in these processes. The goal of these investigations is to develop more specific treatments and, ultimately, curative and preventive interventions. NIMH established a Clinical Neuroscience Research Branch in 1999 specifically to address these issues of translational science and, in the past several years, has significantly expanded its "flagship" translational program—The Silvio Conte Centers for the Neuroscience of Mental Disorders (currently 13 Centers are funded at an annual cost of $24 million).

Carefully controlled, randomized, double-blind trials remain a cornerstone of clinical research sponsored by the NIMH. As practitioners are well aware, however, such studies cannot be the end of treatment research but a beginning. Clinical treatment research must adapt to the changing nature of treatments, patients, and the health care environment. Accordingly, NIMH has launched a series of clinical effectiveness trials that are characterized by large sample sizes and few exclusion criteria; to ensure the generalizability of findings, these trials occur not only in academic clinics but also in more real world settings including primary care settings. The approach also calls for aggressive dissemination of results. Four large-scale, multi-site clinical effectiveness trials include: (1) Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) to investigate strategies for managing bipolar disorder, (2) Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) to study the effectiveness of the new atypical antipsychotics in schizophrenia and Alzheimer's disease, (3) Sequenced Treatment Alternatives to Relieve Depression (STAR*D) to develop algorithms for managing especially difficult to treat depression, and (4) Treatment of Adolescents with Depression Study (TADS). In mid-fiscal year 2003, all of these trials are well on their way to attaining the targeted number of research participants. Through the network of research centers participating in these effectiveness trials, NIMH is creating an infrastructure for future clinical research involving direct comparisons of treatments and their benefits to different populations that can be conducted independently of pharmaceutical companies.

Recognizing that much of the screening for mental illness and treatment is provided in other than specialty settings, NIMH continues to gain a better understanding of cost and financing associated with care in three different settings: juve-

nile justice system, school systems, and primary care. Use of non-traditional settings offer an opportunity to learn new ways of treating and managing co-existing addiction and mental illness problems through the use of non-specialty care providers working with the less numerous specialty providers. Research is also exploring preferences of individuals with mental disorders or combined disorders to seek treatment in general health care, or social services settings and determining if access to treatment in a preferred setting improves seeking treatment, staying in treatment, and adherence to treatment plans.

SCHIZOPHRENIA RESEARCH

Question. Schizophrenia is the most devastating mental illness, affecting approximately 2.2 million American adults, or 1.1 percent of the population age 18 and older. Schizophrenia interferes with a person's ability to think clearly, make decisions, and relate to others. Scientists still do not know the specific causes of schizophrenia, but research has shown that the brains of people with schizophrenia are different, as a group, from the brains of people without the illness. While newer treatments for schizophrenia (including atypical anti-psychotic medications) are proving much more effective in treating both the positive and negative symptoms of schizophrenia, these treatments are largely palliative and help patients better live with, rather than recover from the illness.

Given the enormous public health burden associated with schizophrenia and the need for new treatments, what is NIMH doing to ensure that schizophrenia research becomes a higher priority within the agency?

Answer. Recognizing that schizophrenia is among the most serious public health problems facing Americans, the NIMH has increased the proportion of it's budget devoted to this and other related neurodevelopmental disorders from 16 percent to 23 percent in the last five years. Reflecting the higher priority afforded this severe illness within NIMH, new initiatives have been launched that balance the need to focus on discovering the fundamental cause of the disease so a cure might be possible, with the need to improve treatments for patients who are suffering today.

Efforts to understand the etiology of schizophrenia and other devastating mental illnesses are grounded in the neurosciences. For example, the NIMH Human Genetics Initiative is in the process of collecting biological materials on over 17,000 individuals to create a national scientific resource of DNA for broad use by investigators in the scientific community. Such samples help to identify risk genes associated with schizophrenia and shed light on the mechanisms malfunctioning in the brain. The Research Centers of Excellence (Silvio Conte Centers for the Neuroscience of Mental Disorders) have been established to develop and follow new leads generated by genetic and other basic studies in order to clarify abnormalities in brain functioning associated with major psychiatric illnesses. Over half of these Centers focus on schizophrenia, including two new centers (Mt Sinai and University of North Carolina, Chapel Hill) that have been funded in the last fiscal year.

Although the delusions and hallucinations of schizophrenia are often treated effectively by available medications, research indicates that impairments in cognition (memory, planning, abstract thinking) are most associated with disability in this illness. Unfortunately, available medicines do little to reverse this aspect of schizophrenia. To address this problem, NIMH has launched a Schizophrenia Treatment Development Initiative focused on both developing new drug treatments to remedy cognitive impairments. With the cooperation of the FDA, this initiative will develop standard measures and methods to test new drugs that target cognition in schizophrenia in order to provide the pharmaceutical industry with guidelines for drug registration and hence, enhanced incentives to invest in developing treatments for this aspect of schizophrenia. To jumpstart this effort, in fiscal year 2004 NIMH will establish a new clinical trials network focused on collaborating with industry to identify and test new agents for cognition in schizophrenia.

In addition to the large Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) project, which is designed to determine the long-term effects and usefulness of antipsychotic medications in a broad cross-section of persons with schizophrenia, NIMH is conducting a range of studies concerned with how to best use available treatments for schizophrenia. These include clinical trials of combination medication strategies. Recognizing that medication adherence is a crucial issue for many patients, active efforts to stimulate research on this problem have yielded a series of new studies designed to develop and test adherence-oriented intervention. Finally, rehabilitation-oriented studies are encouraged and supported to develop new approaches to enhancing patient skills and functioning.

FOCUS & ACCOUNTABILITY ON SEVERE MENTAL ILLNESS AT NIMH

Question. Dr. Insel, as you know, NIMH has been criticized in the past for failing to maintain an appropriate focus on severe mental illness in its portfolio. Over the years, concern has been expressed that basic scientific and clinical research on schizophrenia, bipolar disorder and other severe mental illnesses remain low priorities at NIMH. In order to challenge and rebut these criticisms, would you support a requirement for NIMH to provide an accounting of new and existing research grants broken down by specific illnesses?

Answer. First, let me make clear that direct support for research of so-called "serious mental disorders," such as schizophrenia, is a priority at NIMH. It is the lead Federal agency responsible for supporting research on mental and behavioral disorders. The goal of NIMH's portfolio of research on mental illness is to better understand, treat, prevent, and ultimately cure mental illness. This requires both direct and indirect approaches, which may not be apparent in accounting for spending by disease.

Basic research, the relevance of which might not be immediately apparent, can produce knowledge critical for understanding mental illness. For example, studies of the brains of songbirds, brought the unexpected and startling news that adult brains can regenerate new nerve cells, a finding that completely changed scientists' thinking about the possibility for brain repair. Similarly, in October 2000, Dr. Eric Kandel, an NIMH grantee, won the Nobel Prize for Medicine based on his work with sea slugs, in recognition that this research had profoundly increased understanding of brain function and medication effects in humans. Both scientists have accelerated our understanding of brain processes important for mental illness.

Over the years, Congress has expressed interest that NIMH take responsibility for many areas beyond mental illness including HIV/AIDs risk behaviors, violence, gambling, and many others. Nevertheless, NIMH has a strong and abiding commitment to a core focus on severe mental illnesses. Indeed, NIMH has launched four large-scale, public health oriented clinical trials in major disease conditions, including bipolar (manic depressive) illness; schizophrenia/Alzheimer disease; treatment-resistant depression; and major depression in adolescents. These trials investigate "real world" effectiveness of mental health treatments, and because they are carried out in community settings they do not exclude people because they have a co-occurring substance abuse disorder or other problems B unlike typical short-term pharmaceutical trials. People with these disorders live in the community, and NIMH is committed to assuring that treatment interventions will work where the patient lives.

NIMH is supporting many new activities with a focus on severe mental illnesses, and has increased the percentage of its overall research portfolio in this area. One major new initiative, for example, will look at the cognitive deficits associated with schizophrenia B the deficits that make it very difficult for people affected by the disease to be employed or otherwise function fully in society. This is an effort to develop new insights into the neurobiology of attention, working memory, and other fundamental cognitive processes in order to identify and test potential therapeutic agents targeting cognitive deficits in schizophrenia. As a part of this effort focused on schizophrenia, NIMH is establishing an expert Schizophrenia Cognition Measurement Development Group. Without measurement consensus, the Food and Drug Administration cannot recognize cognition as a valid treatment endpoint for industry-sponsored research and drug registration. Since cognitive impairment, rather than delusions and hallucinations, may be the major determinant of functional outcome in people with schizophrenia, this is an extremely important effort. NIMH also will support a Cognition Treatment Network to identify, evaluate, and acquire pharmacological agents to treat cognitive deficits in schizophrenia and related psychoses.

In summary, the goal of NIMH's portfolio of research on mental illness is to better understand, treat, prevent, and ultimately cure mental illness. While the NIMH has significantly increased the percentage of its portfolio devoted specifically to studies related to severe and persistent mental illnesses, it continues to honor its mission and responsibility to support basic biomedical and behavioral research that will elucidate the underlying causes of these disorders. A strict focus on specific diseases would make this very difficult, if not impossible, and would certainly hamper scientific progress.

QUESTIONS SUBMITTED TO THE SOCIAL SECURITY ADMINISTRATION

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

Question. Commissioner, since 1997 the General Accounting Office (GAO) has included the Supplemental Security Income program in its list of programs that are at high risk for waste, fraud and mismanagement. Thanks to the Agency's dedicated effort, GAO's 2003 High Risk Update did not include the Supplemental Security Income program. However, as indicated by your Corrective Action Plan, additional steps can be taken to continue to strengthen program oversight and reduce the incidence of erroneous payments.

What specific actions are supported in the fiscal year 2004 budget request to prevent the occurrence of erroneous payments in the SSI program and strengthen program oversight?

Answer. The President's fiscal year 2004 budget includes appropriation language requiring the Social Security Administration (SSA) to spend no less than $1.446 billion of the Limitation on Administrative Expenses (LAE) for program integrity activities, including continuing disability reviews (CDR), non-disability redeterminations of eligibility in the Supplemental Security Income (SSI) program, and overpayment workloads. This language will ensure adequate resources for these three important and cost-effective workloads that reduce erroneous payments, within the overall SSA request of $8.53 billion. The fiscal year 2004 program integrity investment will return lifetime program savings of more than $10 billion. The three key activities are:

—*Continuing Disability Reviews*.—SSA conducts periodic reviews to ensure that only those beneficiaries who are truly disabled continue to receive benefits.

—*SSI Redeterminations*.—Experience has shown that the most powerful tool SSA has to detect and prevent improper payments in the SSI program is to perform periodic reviews of the non-disability factors of eligibility for SSI.

—*Overpayment Collections*.—Prompt processing of the Agency's debt collection workload is an important element of sound financial management and program stewardship. Having sufficient administrative resources will allow SSA to process substantial overpayment workloads and move forward as quickly as possible to implement new tools of prevention, detection and collection.

SSA's substantial program integrity initiatives result in significant benefits to the Government in terms of detecting and collecting overpayments. Without these program integrity efforts, the Agency would pay out billions of trust fund and general fund dollars in erroneous payments. Experience has shown a $9-to-$1 return on for investments in CDRs and a $7-to-$1 return for investments in SSI redeterminations. Because these activities pay for themselves, many times over, resources to support them shouldn't compete with resources needed for service delivery; and the President's budget proposes funding them through adjustments to discretionary spending caps.

The fiscal year 2004 budget also supports a number of initiatives to prevent and collect erroneous payments in the SSI program and strengthen program oversight, including piloting an automated monthly wage reporting system using voice recognition and touch-tone phone technology, testing electronic access to records of financial institutions, and implementing cross program recovery, credit bureau referrals, and Treasury Department administrative offset.

SSA's fiscal year 2004 budget also contains a legislative proposal to apply the same requirements now in effect for reviewing title II initial disability allowances to title XVI adult disability allowances. Preeffectuation reviews have a high rate of return on investment, would strengthen the integrity of the SSI program and help assure the American people that their tax dollars are going only to individuals who are truly disabled under the law.

Question. How will this budget request fully utilize all of the tools provided by Congress for preventing and collecting erroneous payments, in particular those authorized by the Foster Care Independence Act of 1999? Also, if erroneous payment prevention and collection authorities currently available are not being fully utilized, is it because of a lack of resources available to the SSA? If not, what is preventing SSA from fully utilizing these authorities and what steps are being taken to overcome those barriers to full implementation?

Answer. SSA has a vigorous program for developing all debt prevention and collection tools authorized by Congress. The Agency's program encompasses the authorities granted by the Foster Care Independence Act (FCIA) of 1999, authorities given by other laws, and self-initiated projects. SSA's strategy for implementing all of the tools is to use its available resources first to develop those that yield the most

savings or that can be easily integrated into the existing debt management framework.

The authorities granted by FCIA are: access to financial institutions, credit bureau reporting, administrative offset, establishing overpayments on the records of representative payees of deceased beneficiaries, Federal salary offset, private collection agencies, and interest charging. Authorities granted by other laws include mandatory cross program recovery and administrative wage garnishment.

DEBT PREVENTION

The top two reasons for SSI overpayment errors are unreported wages and unreported bank accounts with substantial assets. In the past, SSA has focused on the detection of errors in payments already made. Initiatives either planned or underway offer substantial promise as a means to preventing error.

—*Automated Monthly Wage Reporting Using Voice Recognition and Touch-Tone Phone Technology*.—The Monthly Wage Reporting Pilot using voice recognition and touch-tone phone technology is one of the steps SSA is exploring to facilitate wage reporting and reduce the incidence of erroneous overpayments in the SSI program. Each year we detect approximately $500 million in overpayments due to wages. Over half this amount is due to the failure to report changes to SSA. SSI recipients are required to report whenever there is a change in their income or the income of a deemor (a spouse or parents of a child under the age of 18 living in the same household but not receiving SSI). Some individuals report changes as required, but many do not. Currently, few SSI recipients have access to the Internet. Therefore, we are testing a new automated telephone reporting system that could quickly process large numbers of wage reports. We will ask approximately 4,000 people to use this new system to report wages once a month for a 6-month period, May through October 2003. We will then verify the wage amounts to determine if they reported accurately. If this test is a success, automated monthly wage reporting will be rolled out nationwide.

—*Access to Financial Institutions*.—SSA will test a process using authority granted by FCIA to access the records of financial institutions. Use of this tool during the initial claims process will provide access to information on unreported income or assets. Similarly, use of the tool during the SSI redetermination process and periodically throughout the life of a SSI recipient's entitlement will provide information regarding a recipient's assets in relationship to limits affecting eligibility. SSA is currently working to finalize the rules for publication, which will enable SSA to proceed with a proof of concept to test the capability of electronic access of financial records later this year. If the proof of concept is successful, SSA will develop plans for a phased rollout of the new business process.

DEBT COLLECTION

SSA is constantly striving to improve its debt management program. Since 1992, when the Agency implemented Tax Refund Offset (TRO) to collect delinquent title II overpayments, SSA has put in place eleven different improvements. These improvements include two major expansions to the TRO program, credit bureau reporting and administrative offset for delinquent title II overpayments and a streamlined remittance process that uses state-of-the-art equipment. In addition, SSA worked with Treasury's Financial Management Service to implement Benefit Payment Offset and the Federal Payment Levy Program, whereby Social Security benefits are offset or levied as collection toward delinquent tax and non-tax debts owed by beneficiaries to other Federal agencies.

—*Recent Initiatives*.—In keeping with its developmental strategy, SSA implemented mandatory cross program recovery in 2002 because of its promise of large debt collections. In fact cross program recovery has enabled SSA to collect over $50 million in SSI debt in less than one year. SSA also implemented credit bureau reporting and administrative offset in 2002 because those tools could be integrated easily into the existing debt management system.

—*Current Initiative*.—SSA also is developing administrative wage garnishment (AWG), which was authorized by the Debt Collection Improvement Act. We believe AWG has the potential to yield the largest amount of collections of all the remaining tools. We estimate this tool will yield $105 million in the first five years of its use ($80 million in title II collections and $25 million in title XVI collections).

—*Future Initiatives*.—When SSA completes its work on AWG, it will move on to a pair of debt collection tools authorized by FCIA: establishing overpayments on the records of representative payees of deceased beneficiaries and Federal salary offset. Although these two tools will yield direct collections from payment

sources such as tax refunds, other Federal payments and Federal salaries, they will not approach the collection potential of AWG, and that is why they will be developed after garnishment.

Implementation of interest charging and use of private collection agencies will follow the completion of Federal salary offset and the establishment of overpayments on the records of representative payees.

FULL UTILIZATION OF FCIA TOOLS

Debt management represents one of the many different areas requiring resources. In fact, SSA has a multitude of initiatives spanning all aspects of its business process. The Agency must prioritize projects and choose the order in which they are developed.

SSA has a process for determining the priority of initiatives. This process is manifested in SSA's Information Technology plan, where projects are assessed based on their return on investment and other critical factors. Based on this rigorous examination of projects, SSA is focusing first on monthly wage reporting, access to financial information and administrative wage garnishment.

Question. The "Justification of Estimates for Appropriations Committees" for the fiscal year 2004 budget request for Social Security Administration (SSA) states that: "The Ticket to Work Program is up and running in 33 States and the District of Columbia and will be expanded to all States and U.S. territories in 2003."

Specifically, how much funding is available within the fiscal year 2004 request for the Limitation for Administrative Expenses account to support implementation of the Ticket to Work program and what activities are supported?

Answer. SSA's fiscal year 2004 LAE account includes $39 million to fund the following activities in support of the Ticket to Work program:

—*Benefits Planning and Assistance Cooperative Agreements ($23 million)*.—Benefits planning, assistance and outreach (BPAO) cooperative agreements are intended to ensure that these community based services are available in every state, the District of Columbia and every U.S. territory. The law authorizes $23 million to be appropriated each year through 2004 for this purpose, and SSA's fiscal year 2004 budget includes funding in this amount (including costs of related training and technical assistance).

—*Protection and Advocacy Grants ($7 million)*.—The 1999 Ticket to Work Legislation authorizes $7 million to be appropriated each year through 2004 for Protection and Advocacy (P&A) grants. These grants will be used to provide advice to beneficiaries and to provide an avenue for resolving disputes. Consistent with the $7 million authorization, we plan to spend $7 million (including costs of support services such as training and technical assistance) for P&A in fiscal year 2004.

—*Program Manager Contract ($9 million)*.—The Program Manager contract was awarded to Maximus Inc. in fiscal year 2000 at a total cost of $56 million covering the period September 29, 2000 through September 30, 2005. Maximus is a private Virginia based organization that will help SSA manage the over-all Ticket to Work program. Phase IV of the contract is funded in fiscal year 2004 at $9.4 million.

In addition SSA's administrative budget supports other Return to Work activities such as:

—The Ticket to Work and Work Incentives Advisory Panel advises the Commissioner of SSA, the President, and Congress on issues related to work incentives for people with disabilities.

—Other administrative costs include quality assurance contracts, notices, miscellaneous printing costs such as public education materials and reference guides, postage, training, travel, and systems enhancements.

—Nationwide training and outreach efforts to build employment support expertise in SSA's field offices. SSA also is looking at its current incentives as they pertain to young people with disabilities who are making the transition from school to work and to disabled individuals with more challenging rehabilitation issues.

Question. How much funding from other sources support the program within the fiscal year 2004 budget request?

Answer. SSA's fiscal year 2004 budget includes program funding to cover outcome and milestone payments made to Employment Networks (EN) under the Ticket to Work program. Milestone payments are provided to ENs based on a beneficiary's successful achievement of prescribed work activity. Outcome payments are made once an individual's benefit payments cease due to work activity and earnings. For fiscal year 2004, we have budgeted $25 million in each program—Social Security (OASDI) and Supplemental Security Income—to cover Ticket payments. In addition,

SSA provides reimbursement payments to State Vocational Rehabilitation (VR) agencies, which elect to be paid under this system and not as ENs, when they are successful in rehabilitating disability beneficiaries. The budget includes an estimated $73 million to cover OASDI VR reimbursement payments and $75 million to cover SSI reimbursement payments in fiscal year 2004.

In addition, SSA's fiscal year 2004 section 1110 research budget request, funded through the SSI appropriation, includes $5.2 million for evaluation of the Ticket to Work and Self-Sufficiency Program. This project will identify the most promising components of the Ticket to Work initiative, the most efficient incentive structure for the program, the refinements necessary to improve Ticket outcomes, and the individuals most likely to benefit from the program. It also will examine the adequacy of incentives in delivering services under the program for hard-to-serve beneficiaries.

SSA's fiscal year 2004 budget for research and demonstration projects also funds several other projects that support the return-to-work initiative and the Ticket to Work program's goal of transitioning disabled individuals into the workforce, including the Youth Transition Process Demonstration, the Early Intervention Demonstration, and evaluation of the Disability Program Navigator project with the Department of Labor.

Question. Now that the SSA has roughly one year of experience with Social Security and SSI disability recipients receiving Tickets for VR services, what trends are evident in terms of the choices consumers are making whether to utilize their ticket, the characteristics of participating individuals, the organizational characteristics of selected Employment Networks (including VR agencies), the way in which such Employment Networks are paid and the employment outcomes for participating individuals?

Answer. Our early information reveals that a fairly diverse group of beneficiaries have made the decision to assign Tickets to providers and to begin employment. So far, the profile of beneficiaries who have assigned Tickets closely tracks the profile of Ticket-eligible beneficiaries with regard to type of benefit, sex, type of disability and time on the rolls. One interesting trend we will be watching is that younger beneficiaries, those under age 40, are assigning Tickets at a much higher rate than older beneficiaries are.

With respect to providers, approximately 85 percent of individuals participating in the Ticket program have assigned their Tickets to the State VR agencies; of these, about 60 percent are new clients to VR. VR agencies have elected to receive payment under the traditional cost reimbursement program for 95 percent of these beneficiaries. ENs with Tickets assigned to them include traditional employment service providers in the public and private sectors, and such non-traditional providers as employers, colleges, employment agencies and job placement services, hospitals, faith-based organizations and Department of Labor One-Stop centers.

As of May 8, 2003, about 4 million Tickets have been mailed, and more than 16,000 have been assigned to ENs or VR agencies. Although we have information regarding payments to providers, it is still too early to draw broad conclusions regarding the employment outcomes of beneficiaries participating in the Ticket program. We will be evaluating the Ticket program to identify its most promising components, refinements needed to improve Ticket outcomes, and the individuals most likely to benefit from the program, as well as to assess the program's cost effectiveness. Nevertheless, many Ticket participants are now working, and we are pleased to learn the success stories from individuals whose receipt of the Ticket has provided them the opportunity to return to productive employment.

By the end of this year, the Ticket-to-Work program will be available in all 50 States. I truly believe that we're entering a new era for people with disabilities—an era of new attitudes, new possibilities, and new hopes. Many people want to work, and this program helps them do that:

—Arizonian, Bob Q., used his Ticket, set up an appointment with an employment network, and is now working as a marketing designer for the real estate industry.

—Didi A. credits the Ticket-to-Work program for helping to provide the motivation that brought her to Arizona Bridge to Independent Living (ABIL). Using her Ticket, she met with a job counselor who prepared her for work. Last September, Didi accepted a position with the Arizona State Government.

—Vera L. has the longest recorded employment of the Ticket Program, more than a year. Vera works 40 hours a week as a personal assistant and has already received a raise.

Question. Through what means has SSA informed eligible beneficiaries and recipients, employers, service providers and other stakeholders about the Ticket program?

Answer. We've informed beneficiaries and recipients, employers, service providers and other stakeholders about the Ticket program through:

—The initial Ticket mailings, which we will complete in 2004;

—Media events to kick-off the Ticket program in several States in the first two rounds of Ticket roll-out. I joined former Senator Roth in Wilmington, Delaware to highlight presenting "The First Tickets in the First State" to individuals in Delaware. I also hosted Ticket media events with Senator Ted Kennedy in Boston, MA and Representative J.D. Hayworth in Phoenix, AZ., and with Virginia State officials in Arlington, VA;

—Partnering with the Office of Personnel Management (OPM) to promote the Ticket program throughout the Federal government;

—Partnering with the Department of Labor's Office of Disability Employment Policy to utilize its Employer Assistance Referral Network and create a subunit named Ticket to Hire (TTH), which specializes in matching employers with job-ready candidates from the Ticket program;

—Partnering with private organizations to promote the program to a diverse mix of employer groups;

—Recruitment fairs to educate service providers about the Ticket program and encourage them to become ENs;

—Significant outreach to service providers and others by MAXIMUS, our contracted program manager;

—Our Internet website, which educates and provides resources to Ticket to Work stakeholders;

—National and regional representation, by specialized Ticket to Work staff, at hundreds of conferences and forums that promote the hiring of people with disabilities; and

—SSA's extensive informational materials provided in print and other formats. SSA's Red Book on Work Incentives and a number of other materials are used extensively in the field to inform and train beneficiaries, advocates, service providers and others.

We are working on further enhancements to our outreach and public information efforts. Plans include written and video presentation of Ticket success stories, a new training effort to assist present and potential ENs with information on potential funding sources and analysis of emerging data on the Ticket program to target our informational efforts.

Question. How much funding within the fiscal year 2004 Budget supports training, technical assistance and outreach to these different groups?

Answer. SSA's fiscal year 2004 administrative budget includes $39 million for BPAO cooperative agreements, P&A grants, and continuation of the Program Manager contract. A large portion of that amount is used to provide training, outreach and public information.

Question. How has SSA provided support to individuals in making well-informed, work-related decisions, as well as in ensuring that their legal rights are protected under new program authorities?

Answer. SSA has a multi-faceted approach to help beneficiaries with disabilities obtain accurate and timely information and support regarding return to work. The approach centers around continued education and training for all direct service employees, the establishment of partnerships with other agencies and organizations, improved workload management and control systems, and the establishment of a corps of full-time Area Work Incentives Coordinators (AWIC). The AWIC will specialize in employment support workloads and services, and serve as the Agency's ombudsman and focal point of contact for advocates.

Two grant programs authorized by the Ticket to Work and Work Incentives Improvement Act of 1999 provide support to individuals regarding their participation in the Ticket program.

BENEFITS, PLANNING, ASSISTANCE AND OUTREACH (BPAO)

SSA awarded 116 cooperative agreements to a variety of community-based organizations for BPAO projects. The goal of the BPAO program is to enable SSA's beneficiaries with disabilities to make well-informed, work-related decisions.

BPAO projects cover every State, Territory, and the District of Columbia. Collectively they employ over 400 Benefits Specialists who explain the complex interrelationship of SSA's benefits, those of other Federal agencies and an individual's local programs. They assess the potential impact of employment on a beneficiary's Federal and State benefits eligibility and overall financial well being. Benefits Specialists then develop a comprehensive framework of possible options and projected results for each as part of the career development process. Benefits assistance in-

volves effective management of benefits as well as problem-solving support as needed. It includes analysis, reassessment, education, advisement and monitoring. Almost 50,000 beneficiaries have received direct services under the program to date.

Outreach activities by the BPAO projects are ongoing efforts to inform beneficiaries, their families, service providers and other stakeholders about the work incentives available. By enhancing awareness and understanding of the supports to be had, the Benefits Specialists alleviate the fear and uncertainty of beneficiaries considering work. The BPAO program has become an important step on the road to economic self-sufficiency for persons with disabilities.

SSA contracted with 3 universities to provide ongoing technical assistance and training to BPAO projects so they may effectively and responsibly serve clientele. Benefits Specialists must pass an intensive 7-day orientation class and successfully complete a field assignment before providing services under the program. In addition, they attend refresher and follow-up courses throughout the award period. This training is necessary to ensure dissemination of accurate and timely information to our beneficiaries. SSA has provided an arena in which persons with disabilities can confidently ask questions of a trained professional who is not a federal employee.

PROTECTION AND ADVOCACY (P&A) GRANTS

The Ticket to Work and Work Incentives Improvement Act of 1999 also granted the Commissioner authority to make payments to P&A systems for the purpose of providing services to beneficiaries with disabilities. Those services include providing information and advice about obtaining vocational rehabilitation and employment services as well as providing advocacy or other services that a beneficiary with a disability may need to secure or regain gainful employment. Under this new program, P&A grantees ensure that beneficiaries' legal rights are protected.

SSA awarded a total of 57 grants to each of the States as well as the District of Columbia, Puerto Rico, the United States Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and one for the Native American community.

In 2002 alone, more than 10,000 beneficiaries with disabilities received P&A services free of charge which ranged from information and referral to legal representation. The P&As gave over two thousand outreach presentations during this period. Through conferences, seminars, publications, websites, and public service announcements on television and radio, the projects made people aware of viable approaches to overcoming employment barriers. Examples of the assistance provided under this program include:

—Fighting discrimination by employers against persons with disabilities;
—Obtaining reasonable accommodations in the workplace;
—Mediating disputes involving job coaches and individual plans for employment;
—Resolving transportation issues related to work;
—Acquiring tuition assistance and accommodations at educational institutions;
—Locating the best Employment Network for a beneficiary's specific circumstances;
—Working to improve Employment Networks' grievance procedures;
—Educating beneficiaries regarding the employment supports and incentives available; and
—Educating the local community regarding the legal rights of individuals with disabilities.

OTHER INITIATIVES

In addition to these programs, SSA plans to create a new position, the Area Work Incentives Coordinator, to provide technical information and assistance to beneficiaries and outside groups and coordinate work incentive-related activities within the field offices of the Area they represent.

At the same time, we plan to provide a customized training curriculum to accommodate training needs specific to each employee's role in administering employment support programs. For example, continuing education on Ticket to Work and related issues of concern to our beneficiaries will allow our public affairs personnel, using their communications skills and community outreach opportunities, to become effective ambassadors for these programs. In addition, our enhanced training will ensure that field and 800-Number personnel will maintain expertise on work incentives and employment support programs to be responsive to inquiries and process actions as appropriate.

SSA is enhancing systems and establishing procedural changes that will assist field personnel in processing actions efficiently and accurately and will provide information to beneficiaries with disabilities who are working or want to work. SSA

is also building these systems to improve workload management control and to provide more management information about beneficiaries with disabilities who are able to return to the workforce. It is important that there be a pool of experts with technical expertise in the complicated issues that can arise with a disability recipient who is pursuing and taking advantage of employment opportunities. But it is equally important that we continue to change the organizational culture to make return-to-work an integral part of the entire Agency's mission.

In addition to providing designated experts, we plan to leverage our resources by heightening the awareness of employment support programs internally and externally and broadening the knowledge of our entire Operations workforce.

Question. How has SSA collaborated with other federal agencies and partners to increase the work opportunities of individuals receiving Social Security and SSI disability payments and what resources are included within the fiscal year 2004 budget request to carry out such activities?

Answer. SSA is collaborating with others in the following research and demonstration projects to increase the work opportunities of individuals receiving Social Security and SSI disability payments. Amounts budgeted for these activities and evaluations in fiscal year 2004 total about $20 million.

—*Youth Transition Process Demonstration*.—SSA will support State projects to test and deliver needed services to young Social Security and SSI beneficiaries with disabilities to assist them in achieving independence.

—*Disability Research Institute*.—One of the goals of this cooperative agreement with the University of Illinois at Urbana-Champaign is to provide research findings in critical disability policy areas, such as return to work strategies.

—*State Partnership Initiative (SPI)*.—States have been testing innovative approaches to coordinating vocational planning and support, employer and employee coaching, financial planning, health and long-term care, and other necessary supports for disability beneficiaries. SSA will be evaluating the effectiveness of these approaches.

—*Disability Program Navigator*.—SSA has partnered with the Department of Labor (DOL) to support Benefit Navigators at DOL One-Stop Career Centers to provide beneficiaries with information on the Ticket to Work program and other SSA work incentives and well as assistance with related programs that may affect their ability to enter and retain employment (Medicare and Medicaid, housing, etc.).

SSA also is collaborating with the U.S. Department of Labor (DOL) to sponsor the Ticket to Hire program. This free nationwide referral service is designed to assist employers in locating and hiring qualified job candidates with disabilities from the Ticket to Work program. Ticket to Hire connects employers to ENs or State VR agencies from SSA's Ticket to Work program with job ready candidates. Ticket to Hire provides the employer with a referral list of ENs in their community. The employer can then contact these organizations to find qualified candidate(s) who are participants in the Ticket to Work program.

Ticket to Hire is a specialized unit of Project EARN (Employer Assistance Referral Network), which is also sponsored by DOL and SSA. If the Ticket to Hire staff is unable to locate organizations with qualified candidates in their database, the vacancy information is shared with EARN. EARN staff then searches a database that includes additional organizations that are employment service providers and may not be participating in the Ticket to Work program.

Question. The fiscal year 2004 budget request proposes obligations of $2 million for Medicare Savings Program Outreach to continue outreach efforts to all new eligible individuals, as well as to a portion of those previously notified. Specifically, what outreach efforts will be undertaken to newly- and previously-eligible individuals? What portion of those previously eligible will be notified in fiscal year 2004 and subsequent years?

Answer. SSA intends to send Medicare Savings Programs outreach letters annually to all new beneficiaries who meet the statutory income test and are not already receiving help with their share of Medicare expenses. SSA will mail outreach letters to two groups of Medicare beneficiaries who were on the roles before the previous letter selection:

—Beneficiaries who had too much income for this help before but now meet the statutory income test (e.g., as a couple there was too much income, but the new widow's income now meets the statutory test); and

—One-fifth of people who received outreach letters before who continue to meet the statutory income test and are not already receiving help with their share of Medicare expenses.

SSA will continue to share electronic files of selected potentially eligible beneficiaries of the Medicare Savings Programs with their servicing Medicaid State agencies.

SSA plans to continue the letter and file-sharing activities described above for new and previous eligibles annually. These activities will ensure that every potentially eligible beneficiary receives an outreach reminder letter at least once every five years and States will receive appropriate information each year.

Question. How has the GAO evaluation of outreach efforts guided development of your proposed fiscal year 2004 activities?

Answer. GAO has not yet shared evaluation data or results with SSA. SSA looks forward to receiving the GAO evaluation as a potential source of information that could be used to improve this process.

Question. Earlier this year, the General Accounting Office (GAO) added Social Security's disability programs to its list of High-Risk programs. Your fiscal year 2004 budget request supports making substantial progress towards national implementation of an electronic disability process—AeDib—by the end of fiscal year 2004 as a means to improving the timeliness of and efficiency associated with disability decisions.

How much funding is included in the request to support the AeDib? GAO has stated (GAO–03–225, page 132) that the agency has had "mixed success in past technology investments." How has the agency's previous experience with major technology investments helped guide the design and implementation strategy for this new initiative?

Answer. The Agency will begin national implementation of the Accelerated Electronic Disability System (AeDib) on January 1, 2004. Over an 18-month period the system will be installed in every State Disability Determination Services (DDS) center in the country. We estimate an initial IT investment of about $150 million during the budget period for AeDib planning, development and implementation. In addition, significant SSA staff effort will be devoted to project as well as related non-IT support costs.

A previous effort to automate the disability process at SSA was called the Reengineered Disability System (RDS). In 1999 Booz Allen Hamilton assessed RDS and made recommendations to the Agency concerning the use of technology to improve future disability processing. AeDib is based on those recommendations.

Many technological lessons were learned from RDS. For example, while RDS was designed to create one processing system for all of the State DDSs, AeDib will not replace the current DDS case processing systems. Instead, each State is upgrading and enhancing its systems in order to accommodate the Electronic Folder.

SSA is building applications that allow the public to file for disability over the Internet. SSA also is creating a fully automated Office of Hearings and Appeals Case Processing and Management System. This system will automate the hearing process from initial receipt through final disposition.

In order to evaluate our progress every step of the way and to continue to meet the goals of the project, each project associated with AeDib has been or will be rolled out in phases. This process allows SSA to gain the experience it needs in order to continue to meet the customer's needs.

To effectively enhance the capabilities of the Electronic Folder and to provide the infrastructure needed for other initiatives, SSA has completed an initial upgrade to its telecommunications infrastructure. SSA also is maximizing the use of Commercial Off-the-Shelf products.

To document and ensure that we target our development work by determining specific areas with the highest paybacks, Booz Allen Hamilton has completed a Cost Benefit Analysis for AeDib.

Question. What actions are planned to ensure that all components, including state disability determination services, have sufficiently trained staff, available technical and program support and adequate resources to implement this initiative and how much is provided within this budget request for these activities?

Answer. AeDib will provide the infrastructure to support paperless and electronic processing of disability claims from initial contact through the hearing decision. To ensure success and ease implementation activities, AeDib has been broken into several interrelated projects.

First, the American public will have the ability to complete disability claims over the Internet. We have already successfully implemented the adult version of the Social Security disability application and medical form. Prior to national implementation, members from the public came to SSA headquarters to test the disability form. Between now and January 2004, we will be adding additional forms to the Internet.

What the Internet provides for the public, the Electronic Disability Collect System (EDCS) provides to field offices. EDCS is used to electronically collect medical infor-

mation previously obtained on paper forms for initial adult and children cases. Regional trainers from across the nation came to SSA headquarters to receive "Train the Trainer" instruction on EDCS. As of February 2003, every field office received EDCS training. Between now and January 2004, additional functionality including hearings and continuing disability reviews will be added to the program.

The next (and most complicated) project is the Electronic Folder. A prototype of the Electronic Folder was completed in October 2002, and pilots are scheduled to run from July 2003 through December 2003. One of the major activities that SSA needed to accomplish to allow the State Disability Determination Services (DDS) to interface with the new Electronic Folder was to provide them with new computer hardware. We accomplished this in September 2002. We provided the hardware training to the DDSs. We are now in the process of upgrading the software. Implementation of the Electronic Folder, combined with EDCS, will significantly change the business process and reduce case processing times.

The last project is to create an automated system known as the Office of Hearings and Appeals Case Processing and Management System (CPMS). Currently OHA has very limited automation. This project will automate the process from initial receipt through the final decision, which will improve case processing and contribute to productivity improvements. We are working closely with our user groups to build a successful CPMS prototype.

Our training strategy also is multifaceted. SSA has conducted AeDib training for regional trainers at SSA headquarters. At SSA headquarters, technical staff has been undergoing extensive training to learn how to use and integrate new technologies.

In order to ensure a successful implementation of the Electronic Folder, SSA will provide onsite technical training and support to the various components. The goal is to ensure that the architecture is operating smoothly and that SSA/DDS staffs supporting the system are provided with expert training. SSA, working with the DDSs, will also provide hands-on business training to all Federal and State components working with the new Electronic Folder.

Our fiscal year 2004 budget includes approximately 300 workyears in order to support these implementation initiatives and meet our goals.

Question. What steps have been taken to secure the privacy of electronic information collected?

Answer. Several steps are being taken to secure the privacy of electronic information for the AeDIB process as well as for other projects SSA is undertaking. Specifically for AeDIB:

—Developers are following the SSA Systems Development Life Cycle, which includes ongoing security review (access controls, separation of duties, integrity, audit trail etc.), on an iterative basis.
—We are currently piloting a secure transport mechanism for disability data.
—A systems manager responsible for the overall project has been named and is drafting a security plan for the project.
—We are in process of awarding a contract for a security risk assessment monitored by the project officer, system manager and security staff.
—We have implemented ongoing monitoring of Electronic Medical Evidence and Security status meetings by Chief Security Officer staff.

Question. What additional steps are being considered to improve the accuracy, timeliness and cost-efficiency of the disability determination process and what is the timeline for their implementation?

Answer. AeDib is one of the key steps SSA is taking to improve the disability process. AeDib rollout will begin in January 2004 and continue for 18 months. While processing time is expected to improve slightly in 2004, this initiative is expected to substantially reduce processing time over the long term.

—AeDib will provide us with tools to move work seamlessly from place to place, increasing access to agency medical and technical expertise, maximizing agency resources, and supporting quality adjudication. The first piece of AeDib is the electronic intake system Electronic Disability Collect System (EDCS) which began in October 2002. By automating data collection, the accuracy of the information will be enhanced and more complete information will be passed to the Disability Determination Services (DDS) and later to the Office of Hearings and Appeals.
—We will be conducting assessments throughout start-up and rollout of the new system and process. Additionally, we will be conducting a post implementation review that will help determine impacts, efficiencies and quality results based on AeDib.
—SSA also is working with the medical community to leverage their electronic processes in coordination with our AeDib medical evidence activities. Our goal

is to increase the electronic exchange of medical evidence to maximize efficiencies in alignment with Health Insurance Portability and Accountability Act (HIPAA) regulations. On May 8, I met with representatives from some of the nation's largest medical professional associations to discuss SSA's medical evidence needs, the process for obtaining evidence, the new HIPAA compliant authorization form, and our vision of a future electronic business process.

SSA has been engaged in a number of efforts to redesign and improve the disability determination process by testing several initiatives over the past several years. Based on our review of their results, we have decided to:

—Encourage early and frequent contacts with claimants during the development process;

—Eliminate the claimant conference at the end of the process; and

—Temporarily extend the "elimination of reconsideration step" feature in the Prototype States that are currently doing this, while SSA develops an alternative approach.

The amount of time the SSA appeals process takes also has been a major concern. SSA has made the following near-term changes to the hearing process, based on analysis of the Hearings Process Improvements (HPI) initiative:

—Include ALJs in early case screening to more quickly identify cases for dismissal and possible on-the-record decisions;

—End the requirement that cases be certified as "ready to hear", removing a step in the process;

—Allow ALJs to issue fully favorable decisions from the bench immediately after a hearing; and

—Expand the use of technology in the Office of Hearings and Appeals, including video teleconferencing, speech recognition and digital recording of hearings.

SSA also is assessing its policies and procedures to enable simplification of data collections and case documentation. We have revised and consolidated data collection forms to ensure consistency and accurate data propagation. For example, we are combining 3 forms into a single public-use document as part of the appeals process.

SSA currently reviews at least 50 percent of all title II initial disability allowances made by State agencies on behalf of SSA. The fiscal year 2004 President's budget includes a proposal to apply the same requirement for adult disability allowances in the SSI program. That is, when fully phased in, 50 percent of initial SSI disability allowances would be reviewed, applying consistency across both disability programs.

We expect to make recommendations soon regarding additional steps we can take to improve the disability process.

Question. Commissioner, you have stated that the Hearings Process Improvements (HPI) initiative, which was implemented in 2000, has not worked and that SSA has implemented additional changes to the process, based on your assessment of HPI.

What lessons has SSA learned from the failure of HPI and how were they used to develop and implement the latest changes?

Answer. What we learned during the course of HPI has yielded insights valuable to the further refinement of our hearings processes. We have not yet implemented our contemplated mid-term and long-term process changes. Therefore, these responses chiefly address changes we have made in the short-term.

We learned that the HPI processes included unnecessary case handoffs. In our latest changes, we sought to eliminate these handoffs. For instance, we observed that attorney and paralegal certification of cases as "ready to hear" before sending those cases to Administrative Law Judges (ALJs) for prehearing review was a step of limited value. We have eliminated that step. Though we had initially thought that rotating functional assignments among support staff would improve overall hearing office performance, we discovered that rotation actually undermined the strengths of our staff. Consequently, we discontinued rotations and created a new position, the Case Intake Assistant, with duties that incorporated the previously rotated functions.

HPI taught us the importance of a strong management team in the hearing offices. We are striving to strengthen the management structure in the field. HPI also taught us the importance of prompt implementation of systems support needed to support new initiatives. We are proceeding as expeditiously as possible with the development and implementation of new technology and applications to support the Office of Hearings and Appeals' (OHA) business processes.

Question. Given that implementation of reforms is very costly in terms of additional delay for individuals involved in the process, lost production time, and staff anxiety, what steps were taken to involve all stakeholders in the latest reform and

what resources are included in the fiscal year 2004 request for staff training and support of implementation?

Answer. We haven't undertaken a major reform of the hearing process since HPI. However, we recognize there are significant hearing backlogs and we need to make every effort to move toward reducing those backlogs. For this reason, with the proposed transfer of Medicare hearings to the Department of Health and Human Services in fiscal year 2004, this budget redirects 478 workyears previously used to process Medicare hearings to processing SSA disability hearings and appeals instead. This will enable SSA to process 46,000 more SSA hearings in fiscal year 2004 than in fiscal year 2003 and improve service by reducing the hearings processing time.

We have focused on processing the work with incremental initiatives that could be effectuated in the short term with little delay for individuals involved in the process and minimal, if any, loss of production time. We believe the nature of these changes, our candid discussions with all of the unions representing our employees, and the initiatives' incremental implementation over the past year have helped to minimize any potentially adverse impact on employee morale and productivity. And, despite additional investments in training, savings from initiatives will increase the overall production rate for SSA hearings from fiscal year 2003 to fiscal year 2004.

The budget continues to support base levels of ongoing and new staff training for OHA staff, plus significant training for technological enhancements to the business process in fiscal year 2003 and fiscal year 2004, including training related to implementation of AeDIB. Most of the cost of staff training is the workyear cost, along with related non-payroll expenses for instructors and travel. For fiscal year 2004, we estimate about 250 workyears for OHA training, including about 100 workyears related to AeDIB.

Question. How will the latest reforms improve timeliness, accuracy and efficiency of decision making? What other changes have been implemented to help improve productivity and increase the likelihood of getting the right decision at the earliest possible time?

Answer. We are preparing cases for hearing more quickly and in greater numbers with the aid of contract file assemblers, who furnish clerical support for file preparation. As previously noted, we also have eliminated rotational assignments for case technicians. These actions free case technicians to concentrate their attention on more complex case preparation tasks.

We have asked our most highly trained employees, ALJs, to join other professional hearing office employees in early screening and reviewing cases most likely to warrant on-the-record decisions. ALJ participation in this process facilitates review of a higher percentage of such cases, thus increasing the number of cases that can be decided early, without the necessity of a hearing.

We have implemented a new decision writing program for fully favorable decisions that is easy for ALJs and decision writers to use and fully documents the legal basis for fully favorable decisions. Providing the new program as a tool for their use, we have asked ALJs to use their personal computers to draft any fully favorable decisions they reach as a result of early screening, as well as any decisions that they announce orally at a hearing. This eliminates case handoffs to the decision writers and frees the decision writers to concentrate on more complex cases.

We are providing speech recognition software to ALJs and decision writers to facilitate decision drafting. The introduction of this software will eliminate the need for transcription of dictated decisions by case technicians, shortening case processing time and freeing the case technicians for case preparation duties.

Question. The GAO Report "Social Security Disability: Efforts to Improve Claims Process Have Fallen Short and Further Action is Needed" (GAO–02–826T) found that in fiscal year 2000, about 40 percent of the applicants whose cases were denied at the initial level appealed this decision and about two-thirds of those who appealed were awarded benefits. What resources and activities are supported in the fiscal year 2004 budget request to specifically address this issue and reduce the likelihood that initial decisions are changed upon appeal?

Answer. Our goal is to make the right decision on disability claims as early in the process as possible. We should note, however, that a different decision during the appeals process does not necessarily mean that the initial decision was wrong when it was issued. Unfortunately, currently many months may elapse between the initial determination and the various steps of the appeals process and, during that time, the claimant's medical condition may have worsened. And, we allow a claimant to provide additional information at any time during the process. So a person who may not have met the criteria for disability assistance at the first step may meet those criteria by the time a hearing can be held. This kind of situation shows the importance of reducing the delays and backlogs that currently make the appeals process take so long. (We also are working on finding ways to ensure that complete

information is provided at the initial determination step so that the decision-maker can consider all factors that may affect the decision.) For this reason, I have made eliminating backlogs a primary focus.

As I indicated in my testimony at the March 4, 2003 House appropriations hearing before the Subcommittee, the President's budget request for fiscal year 2004 demonstrates our commitment to continuing efforts to improve service, efficiency and program integrity in the disability program. Issues regarding the appeals process and reducing the likelihood that initial decisions are changed upon appeal are longstanding concerns in the disability program. We expect to make recommendations that address those issues in the coming months, and expect to propose changes that are cost-neutral in terms of the overall impact on SSA's budget.

In order to effectively address the systemic issues in the disability process, we need to get the existing disability workloads under control. Based on the work that has been done on our Service Delivery Assessment, it is clear that eliminating backlogs and processing special workloads are prerequisites for providing good service to the public. Although approximately 40 percent of disability claims are approved within three and a half months of initial application, for applicants who exercise all administrative appeal rights provided under current law and current processes, an average of 1,153 days is required for a final Agency decision. Based on our analysis, almost 50 percent of this time in the process results from the backlog of cases.

We are taking a number of actions in the near term to reduce processing times and increase efficiency. The fiscal year 2004 budget request supports those actions. As indicated above, we are engaged in review of strategies to further improve the disability program and expect to make recommendations soon.

Question. The fiscal year 2004 President's Budget proposes to transfer responsibility for Medicare hearings from SSA to the Department of Health and Human Services (HHS).

What are the actual expenditures and associated workload processed in fiscal years 2000, 2001 and 2002, as well as those estimated in fiscal year 2003?

Answer. The chart below provides actual expenditures and associated workloads for Medicare hearings for fiscal years 2000, 2001 and 2002 as well as those estimated for fiscal year 2003 in the fiscal year 2004 President's budget. The estimates for fiscal year 2003 assume an increase in receipts related to the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) and implementation of a streamlined process for handling Medicare appeals. Neither of these has occurred.

Medicare hearings	Actual fiscal year			Estimate fiscal year 2003
	2000	2001	2002	
Receipts	77,872	77,726	71,576	122,147
Processed	88,084	69,663	77,388	105,000
Pending	35,904	43,517	37,705	54,852
Expenditure (dollars in millions)	$79	$74	$78	$79

Question. What planning and transition activities are being undertaken with HHS/CMS to ensure that a timely and smooth transition occurs, if legislation is enacted that transfers the Medicare appeals function effective October 1, 2003 as proposed in the President's budget?

Answer. While we have agreed with HHS/Centers for Medicare and Medicaid Services (CMS) in principle to transfer responsibility for the Medicare hearings function effective October 1, 2003, we are still working out the details of the workload transfer. In January 2002, I established an executive level position on my staff to work directly with the CMS Administrator and his staff to provide technical assistance in the design of a hearing process and service delivery plan tailored to the unique needs and opportunities of Medicare appeals. SSA and HHS/CMS have had an ongoing dialogue since that time. These discussions focus on issues such as transfer of cases, sharing of resources (e.g., video teleconferencing), and systems support. A Memorandum of Agreement that will reflect these decisions is being prepared.

Beginning with fiscal year 2004, consistent with the Administration's plan to transfer the Medicare hearings function to the Department of Health and Human Services, SSA's annual budget request does not include the resources that would be needed to process Medicare hearings. The President's budget now includes the Medicare hearings function and related funding under the Department of Health and Human Services, which is accountable by law for management and administration of the Medicare program.

Question. What amount of budget authority is required in fiscal year 2004 to process fully this workload, if legislation is not enacted consistent with the President's budget?

Answer. Funds to process Medicare hearings are budgeted in HHS/CMS for fiscal year 2004. Consistent with our assumption that HHS/CMS will assume responsibility for the Medicare hearings function beginning October 1, 2003, SSA has not included any resources in its fiscal year 2004 budget request to process this workload.

Question. In January 2001, the General Accounting Office identified strategic human capital management as a governmentwide high-risk area.

What steps are you taking to acquire, develop, and retain an appropriate mix of agency staffing/talent, particularly in light of the Agency's impending retirement wave? What is the agency's plan for creating an organizational culture that promotes high performance and accountability and empowering and including employees in setting and accomplishing programmatic goals? How does the fiscal year 2004 budget support these activities?

Answer. SSA is taking a number of steps to acquire, develop, and retain an appropriate mix of agency staff.

SSA started retirement wave analysis and planning over five years ago. This analysis was the impetus for our Future Workforce Transition Plan (FWTP), which positions us well to transition to the workforce of the future. The FWTP contains milestones regarding recruitment, retention, employee development and a satisfying work environment. It is aligned with our mission, goals and objectives and is integrated in budget, strategic and performance plans. Selected highlights of our activities include:

To acquire staff, SSA:

—Created a national recruitment coordinator position with responsibility for developing and implementing recruitment initiatives SSA-wide;

—Uses recruitment and retention incentives, including above minimum starting salaries, recruitment bonuses, relocation bonuses and retention allowances;

—Uses delegated expedited methods to reduce the time it takes to fill jobs, and continues to work with the Office of Personnel Management to find ways to accelerate the staffing process;

—Is piloting a competency-based hiring process;

—Fills vacancies as early as possible in the fiscal year, subject to budget and hiring authority; and

—Rehires experienced annuitants in times of critical need.

To develop and retain staff, SSA:

—Incorporates organizational values into entry level training and new hire orientation;

—Offers extensive technical and leadership training via Interactive Video and the Intranet. Personal development courses are also available online and can be taken at home.

—Is restructuring curricula around identified competencies to ensure that employees have the knowledge and skills to respond to emerging needs;

—Has a variety of career paths for employee advancement;

—Offers career counseling services;

—Offers national Leadership Development Programs designed to build identified leadership competencies for GS–9 through GS–14 employees, as well as a Senior Executive Service (SES) Career Development Program designed to develop executive leadership in the Agency's succession planning efforts. SSA's organizational components also have a variety of development programs at various grade levels nationwide; and

—Offers SES development opportunities outside of the formal programs.

SSA is creating an organizational culture that promotes high performance and accountability and empowering and including employees in setting and accomplishing programmatic goals. SSA's revised SES performance management system is linked to strategic goals and distinguishes between high and low performance. A revised system for non-bargaining unit GS–15s will be implemented October 1, 2003. An executive level workgroup is currently developing alternative performance systems models for all other employees, taking into account the connection with the awards and promotion systems. Plans for all other employees will take effect with the signing of a new labor contract with AFGE in fiscal year 2004.

Also, SSA sets programmatic goals through our strategic planning process. This process considers our responsibilities to the public we serve and environmental factors such as demographics, health and disability trends, technological advances and workforce trends. Our employees are key to success in accomplishing these programmatic goals. They are actively encouraged to offer suggestions through our

newly automated suggestion program. They are invited to participate on workgroups or provide input as we develop and test new processes.

Additionally, in early fiscal year 2003 I held a series of 11 candid, interactive meetings with all supervisors, managers and executives in the Baltimore/Washington headquarters area, discussing leadership principles, management philosophy and the Agency's four major performance areas. During the summer of fiscal year 2003, I plan to discuss this same set of critical topics with the full management cadre in each of the 10 regional office cities and from field offices in commuting distance of those cities.

The fiscal year 2004 budget supports these activities with a consistent level of baseline funding to accomplish many of the activities cited. Consistent with actual spending in fiscal year 2002, the fiscal year 2004 budget also includes approximately $4 million in project-specific funding for the following initiatives:

—Interactive Video Teletraining
—Leadership Development Programs: Senior Executive Service, Advanced Leadership Program, Leadership Development Program, and Presidential Management Intern Program;
—Leadership Seminars
—Performance Management Training

SSA's budget also provides funding for participation in LEGIS Fellows Programs, OPM Management Development Programs and Federal Executive Institute programs. Funding to maintain the recruitment marketing program developed in fiscal year 2002 and to advance the competency-based recruitment initiative also is included in the budget.

Question. The Congress appropriated additional funds from fiscal year 1996 through fiscal year 2002 to ensure that the Agency would carry out a 7-year plan to become current in processing CDRs. The fiscal year 2004 request includes dedicated funding of $1.4 billion, for among other things to process continuing disability reviews.

Is the Agency on schedule to remain current with processing CDRs in fiscal year 2003?

Answer. In fiscal year 2003, SSA is focusing on keeping up with claims workloads so that the number of disability claims pending does not grow. Consequently, we will not be able to process all CDRs necessary to remain current. We began this year under a continuing resolution and operated for four months at last year's level. In addition, we are absorbing an across-the-board rescission of .65 percent and a higher-than-budgeted pay raise. Nevertheless, we will continue to assess our ability to process more CDRs in fiscal year 2003 than reflected in the fiscal year 2004 President's budget, while keeping up with claims receipts, and will increase the number of CDRs processed to the extent that we are able.

Question. What lessons did SSA learn during this 7-year period about efficiently using these funds to stay current with its CDR obligations?

Answer. If SSA is adequately funded for CDRs we can stay current with this workload. However, we also have learned that we need to work closely with the States and balance the resources applied to CDRs with those for processing initial claims. We have been unable to keep up with incoming disability claims receipts since fiscal year 1997. This situation was compounded by a recent surge in initial receipts. As a result, DDSs entered fiscal year 2003 with the highest initial pending level in DDS history. Currently, it is difficult to ensure adequate funding for stewardship activities when they compete for the same discretionary dollars. Specifically, we face two significant competing demands: (1) the need to pay disabled claims as quickly and proficiently as possible; and (2) the need to serve as stewards of the public trust and perform CDRs to protect program integrity in our trust fund and general fund programs.

The discretionary funding cap adjustments for CDRs authorized by Congress for fiscal years 1996 through 2002 were crucial to realizing currency for both the title II and title XVI disability review programs at the close of fiscal year 2002. The discretionary spending cap adjustment for CDRs and other integrity workloads that the President is recommending in the fiscal year 2004 budget would ensure adequate funding for the future to maintain currency with CDRs and process other cost-effective program integrity work thereby, enabling SSA to meet both its stewardship responsibilities and overall service demands.

The Agency would not have achieved currency at the close of fiscal year 2002, nor will it be able to remain current in the future, without the CDR profiling/mailer process. SSA uses highly skilled statistical support from contractors in performing the statistical analyses that determine who can be sent a CDR mailer, what action to take (automated decision logic) when a CDR mailer is returned, and many of the automated functions of both CDR mailer and full medical processing. SSA has a

wealth of data at its disposal resulting from hundreds of thousands of CDR decisions. Over the past several years the contractors' products have enabled SSA to perform mailer, rather than full medical reviews, for several hundred thousand additional CDRs than was possible in the first few years of the 7-year plan.

The CDR mailer process involves little public burden (it is estimated to take approximately 15 minutes to read the instructions and complete the form), and it is also cost-effective. Agency budget documentation indicates that the unit cost of a CDR mailer in fiscal year 2001 was $27, while the unit cost of a full medical review was $689. In fiscal year 2001, the CDR mailer accounted for over 50 percent (about 895,000 of 1,731,000) of reviews reported to Congress. In fiscal year 2001 alone, even if the Agency had the workforce capacity, an additional 895,000 full medical reviews would have cost an additional $592 million when compared to processing the same number of CDR mailer deferral actions. (The Agency did not have the workforce capacity that would have allowed us to accomplish these medical reviews had there been funding available.)

Since its inception, integrity sampling has been a key element in assuring that the process is a legitimate alternative to a full medical review. The CDR mailer process undergoes continuous, rigorous studies and audits, including yearly audits by PricewaterhouseCoopers as agent for SSA's Office of the Inspector General.

Question. What is SSA's plan for remaining current this year and in the future for processing CDRs?

Answer. As previously indicated, in fiscal year 2003 SSA is focusing on keeping up with claims workloads and therefore will not be able to remain current with CDRs this year. SSA plans to include sufficient resources in its budget requests to maintain currency with CDR workloads. In support of that goal, the fiscal year 2004 President's budget includes earmarked funding of $1.446 billion for SSA program integrity workloads, including CDRs, and a proposal to treat this funding outside the discretionary spending caps.

Question. Please provide the subcommittee with a breakdown of the administrative costs associated with legislative proposals included in the fiscal year 2004 budget. Are these costs fully covered within the fiscal year 2004 budget request for LAE?

Answer. The President's fiscal year 2004 budget for SSA includes eight legislative proposals, only one of which would have significant administrative costs for SSA. That is the proposal for implementation of pre-effectuation reviews (PER) of SSI adult disability allowances, similar to the reviews now in place for Social Security disability program allowances. SSA's fiscal year 2004 LAE request includes $10 million to implement SSI PER. Generally, SSA's administrative budget requests to Congress are based on current law. We have made an exception to the general practice in this case, due to the likelihood of enactment of SSI PER, based on the progress of this proposal in the 107th Congress and now in the 108th. Implementation of SSI PER will yield substantial program savings.

The other SSA legislative proposals are as follows:

—Improved reporting of pension income from non-covered employment—The Administration is working to determine the best way to obtain noncovered pension information systematically from State and local government employers, for enforcement of the Windfall Elimination Provision (WEP) and Government Pension Offset (GPO) provision of the law. The details of the proposal are still being developed.

—Close the loophole that allows exemption of spouses from the GPO based on one day in covered employment.

—Trust fund compensation for Military Service Wage Credits—This proposal makes the trust funds whole for FICA tax equivalents that remain unpaid by the Department of Defense for 2000 and 2001, including appropriate interest, together with adjustments for prior years. There is no administrative impact.

—SSI Program proposals:

  —Exclude from determination of individual income all interest and dividend income earned on countable liquid resources and revise the infrequent and irregular income exclusion.

  —Remove the restriction on payment of benefits to children who are born or who become blind or disabled after military parents are stationed overseas.

  —Treat all cash military compensation as earned income.

  —Count nonrecurring income only for the month it is received during the transition to retrospective monthly accounting during the first three months of eligibility.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you all very much. The subcommittee will stand in recess to reconvene at 9:30 a.m., Wednesday, April 9, in room SD–138. At that time we will hear testimony from the Honorable Elaine L. Chao, Secretary, Department of Labor.

[Whereupon, at 11:10 a.m., Tuesday, April 8, the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, April 9.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2004

WEDNESDAY, APRIL 9, 2003

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:35 a.m., in room SD–138, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Byrd, Harkin, and Murray.

DEPARTMENT OF LABOR

OFFICE OF THE SECRETARY

STATEMENT OF HON. ELAINE L. CHAO, SECRETARY OF LABOR

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Ladies and gentlemen, the Appropriations Subcommittee on Labor, Health and Human Services, and Education will now proceed. This morning, we have the distinguished Secretary of Labor.

Secretary Elaine Chao was sworn in on January 31, 2001, the 24th Secretary of Labor. She had been president and CEO of the United Way Foundation, served as director of the Peace Corps and Deputy Secretary for the Department of Transportation under President George H. W. Bush, distinguished fellow at the Heritage Foundation, MBA from Harvard Business School and an undergraduate degree from Mount Holyoke. She has also studied at MIT, Dartmouth, and Columbia University. She is a veritable Ivy League participant.

Madam Secretary, we welcome you this morning. We are examining your budget and the activities of your Department, and it is always a difficult matter to allocate funding, but the subcommittee is concerned that the discretionary budget request for fiscal year 2004 is more than $368 million under the current budget, and we realize that budgets are established by the Office of Management and Budget of the administration, but we express concern about decreases and elimination of programs. The dislocated worker assistance program is down by more than $78 million, and that's a very difficult area. Just yesterday at a hearing of the Steel Caucus we heard the concerns of dislocated workers who were being impacted

by the acquisition of Bethlehem Steel by the International Steel Group.

We note the elimination of a program on reintegration of youthful offenders, which in my view is a very important program, trying to take youthful offenders out of the crime cycle, something I worked with for many years as District Attorney of Philadelphia, and have on the Judiciary Committee, and the elimination of the program of youth opportunity grants, cuts in mine safety and health, a tough issue. We had an enormous problem in my State, Somerset County, with a mine disaster last summer. This subcommittee held hearings there, and cuts in that program are troubling. Cuts in the OSHA training grants and the job training pilot program and international labor affairs are all matters of concern to the subcommittee.

With those opening comments, Madam Secretary, we are pleased to have a chance to discuss these issues with you in an ongoing relationship, and we now look forward to your testimony. The floor is yours.

SUMMARY STATEMENT OF HON. ELAINE L. CHAO

Secretary CHAO. Thank you, Mr. Chairman. I hope you will not let the Ivy League background be held against me.

Senator SPECTER. I would consider it very much in your favor, having some association myself.

Although the days I spent at the University of Oklahoma, which has been very non-Ivy League compared to the fancy Yale Law School or the fancy University of Pennsylvania, I think non-Ivys have a lot to recommend them, too, but so do we Ivys, Madam Secretary.

Secretary CHAO. Mr. Chairman, thank you for the opportunity to present the Department of Labor's fiscal 2004 budget. The focus of this budget can be summarized in two words, employment and enforcement. The fiscal year 2004 budget and the President's Economic Growth Package reflects this administration's commitment to helping Americans find good jobs and to ensuring that our workers remain skilled, safe, and fairly compensated.

The total request for the Department in fiscal year 2004 is $56.2 billion in budget authority and 17,503 FTE, of which $11.5 billion is the discretionary portion.

The Department is proposing several changes to the Workforce Investment Act which we believe will improve accountability, eliminate duplication, enhance the role of employers in training and placement, and increase State flexibility. We request $2.6 billion for youth employment and training programs to help young people make a successful transition to the world of work, family, and responsibility.

The proposal includes $1 billion for a reformed youth grants program. Twenty percent of these funds will be set aside for challenge grants to cities and rural areas experiencing unique youth development needs. $3.1 billion is requested for adult employment and training programs. As part of WIA reauthorization, we propose to consolidate adult dislocated worker State grants together with employment services. This will give States the flexibility to target re-

sources where they're needed most, eliminate duplication, and serve more participants than ever before.

In addition, we request $47 million to increase marketplace demand for people with disabilities as part of the President's New Freedom Initiative. Some of these funds will be used to test a new pilot disability employment survey by BLS and the Office of Disability Employment Policies. This administration is also strongly committed to meeting the employment needs of our veterans. We requested $220 million and 250 FTE to maximize employment opportunity for veterans and to protect their employment rights when they return.

These are just a few highlights of the Department's proposed employment and job training initiatives, which are described in much greater detail in my written statement.

WORKER PROTECTION

Enforcement of the worker protection laws is both an obligation and a priority of this Department. During our tenure, wage and hour enforcement has achieved new records. Last year, we recovered $126 million of pension assets for beneficiaries, and occupational injury and illnesses rates have reached historic lows, but as we all have said, more can be done.

Among our requests is included an increase in certain civil money penalties for MSHA and Wage and Hour, $5.3 million for OSHA's expanded outreach and assistance program, including specific funding for outreach to non-English-speaking employers and employees, strengthening MSHA's enforcement, education, and compliance assistance programs for small mines, an additional $12.3 million and 69 FTE to enhance enforcement in the Employee Benefits Security Administration, and $2.5 million and 20 FTE to strengthen the Inspector General's request for labor and racketeering initiatives.

The cornerstone of worker safety is OSHA and the Mine Safety and Health Administration. Consistent with their goals, OSHA and MSHA will continue to focus on the most serious hazards and dangerous workplaces. Requests for the Department's other enforcement agencies are detailed in my written statement.

The Department's 2004 budget, of course, also includes initiatives for implementing the President's Management Reform Agenda and, as I mentioned at the beginning of my statement, I believe that the President's fiscal year 2004 budget request for the Department reflects the administration's strong commitment to helping Americans find jobs and to strengthening enforcement of our employment laws.

And with that, thank you very much for inviting me to be here today, Mr. Chairman, and I will be glad to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF HON. ELAINE L. CHAO

Mr. Chairman, and distinguished Members of the Subcommittee, thank you for the opportunity to appear before you today to present the Department of Labor's fiscal year 2004 Budget.

The Department of Labor (DOL) continues to heed the call of President George W. Bush that "Government should be results-oriented—guided not by process but guided by performance." The Department's fiscal year 2004 budget was developed

with just such a focus—and the outcome is the Department's first-ever integrated performance budget.

With the ongoing war against terrorism and the related conflict in Iraq, every department of the government must continue to take a hard look at all of its programs. We must provide more funding for those programs that work; reform and revitalize those that can be improved; and cut or eliminate those that have not proven effective, are duplicative of other programs, or are not currently a great national priority. The Department's budget was developed with this outlook in mind.

The total request for the Department in fiscal year 2004 is $56.2 billion in budget authority and 17,503 full-time equivalents (FTE). The request for the Department's discretionary programs is $11.5 billion.

The Department's fiscal year 2004 budget was developed around four critical themes designed to make a difference in the lives of America's working families: *Helping Americans Find Jobs; Protecting Americans' Employee Benefits; Protecting America's Workers; and Bringing DOL into the 21st Century*.

Helping Americans Find Jobs

In 2003, the Administration will use the opportunity presented by the expiration of the Workforce Investment Act (WIA) to make significant improvements in Federal job training and employment programs. These reforms will improve accountability; eliminate duplication through program consolidation; enhance the role of employers in the national workforce system; and increase state flexibility.

This theme will be further accomplished through Personal Reemployment Accounts (PRAs) for job seekers who are at risk of exhausting their Unemployment Insurance benefits. The President's economic growth plan, released January 7, 2003, includes $3.6 billion for this new tool, which states will have considerable flexibility to design. The accounts will provide up to $3,000 to job seekers to allow them to purchase the training, re-employment, or supportive services needed to get back to work.

The fiscal year 2004 budget and the President's Economic Growth package reflect the Administration's commitment to assisting American workers find and keep work—and will accomplish the Department's first focus of helping Americans Find Jobs. Through funding for job training, a new initiative to help unemployed workers, and reform of existing programs, the Administration is improving opportunities for American workers. The 2004 budget proposes a major overhaul of the administrative structure of the Unemployment Insurance (UI) system, which is an unwieldy relic that badly needs an overhaul. This proposal would make the UI system more responsive to the needs of workers and employers by giving states flexibility and control.

PROTECTING AMERICANS' EMPLOYEE BENEFITS

Effective last month, the Department changed the name of its Pension and Welfare Benefits Administration to Employee Benefits Security Administration, or EBSA. This was done to better reflect the agency's mission and direction. Though newly named, EBSA continues to lead the way in protecting workers' health and retirement security.

As I will touch on later, this budget includes resources to enhance employee benefits and retirement security. With these additional resources, EBSA expects to dispose of 19 percent more civil and criminal cases compared with fiscal year 2003 and restore, protect, or recover $69 million more in pension plan assets. This proposal to increase the EBSA budget—at a time when other national priorities such as the war on terrorism and homeland security are so compelling—is a reflection of the Administration's commitment to protecting workers' and retirees' benefits.

In fiscal year 2004, the Department's Office of Inspector General will continue its role in bolstering DOL's efforts related to this theme through initiatives aimed at achieving the OIG strategic goal of safeguarding and improving worker and retiree benefit programs.

PROTECTING AMERICA'S WORKERS

While occupational injury and illness rates have reached historic lows, more can and must be done. In fiscal year 2004, DOL will continue to balance enforcement and compliance assistance activities through the ongoing efforts of its Occupational Safety and Health Administration (OSHA); Mine Safety and Health Administration (MSHA); the Employment Standards Administration's Wage-Hour Division, Office of Federal Contract Compliance Programs (OFCCP), and Office of Labor Management Standards (OLMS); and the Office of Inspector General (OIG). Initiatives include:

—Strengthening existing enforcement by proposing increases for certain Civil Monetary Penalties under MSHA and Wage and Hour;
—$5.2 million and 3 FTE to expand and improve OSHA's outreach and assistance, including efforts to reach non-English-speaking and contingent workers, provide small business assistance, and increase the number of Voluntary Partnership Programs;
—Strengthening MSHA's enforcement and creating a new Small Mine Office to provide information and assistance to small mining operations; and
—Related efforts include the OIG's Labor Racketeering Initiative, to which $2.5 million and 20 FTE will be applied in fiscal year 2004 to address union corruption.

BRINGING DOL INTO THE 21ST CENTURY

The final theme of the Department's fiscal year 2004 budget will be accomplished by several initiatives related to the DOL's ongoing implementation of the President's Management Agenda. These include a $20 million, first-year investment in a new department-wide accounting system for the Office of Chief Financial Officer, which will update and improve Departmental financial management. $48.6 million is also requested in fiscal year 2004 for the Department's successful Information Technology Initiative, which will, in part, consolidate all DOL agency requests in support of the President's Management Agenda component Expanded E-Government. For fiscal year 2004, $23.5 million is also requested for the Department's Management Initiative to centrally manage DOL's efforts on implementing the other four government-wide initiatives on the President's Management Agenda.

Further, in fiscal year 2004, DOL intends to resubmit two legislative proposals to restore the solvency of the Black Lung Trust Fund and improve and update the Federal Employees' Compensation Act (FECA). Because it integrates administrative and worker benefit costs and provides an incentive to improve workplace safety, the fiscal year 2004 Budget also re-proposes the FECA Surcharge.

The Department will also continue to advocate viable options to reform its Unemployment Insurance program and will support legislation allowing employers to offer employees the option of taking paid time off in lieu of receiving overtime pay.

EMPLOYMENT AND TRAINING PROGRAMS

Overall, the fiscal year 2004 discretionary request for the Department's Employment and Training Administration is $9.2 billion in discretionary funds and 1,360 FTE. The fiscal year 2004 budget request for Employment and Training Programs is $6.389 billion in new budget authority.

These resources will be combined with the estimated 2004 spending of $2.0 billion on Personal Reemployment Accounts included in the President's Economic Growth Package.

Youth

A total of $2.6 billion is requested in fiscal year 2004 for employment and training programs for Youth. This investment will help young people make a successful transition to the world of work and family responsibility. This proposal reforms the youth program through reauthorization of WIA. The reformed Youth Grants program will be funded at $1.0 billion, the same level at which Youth Activities is funded in fiscal year 2003. Twenty-five percent of the Youth funds will be used to provide Challenge Grants to promote collaborative and innovative approaches to preparing youth for success in the labor market.

Adults

A total of $3.1 billion is requested in fiscal year 2004 for employment and training programs for Adults. The proposal reflects a new program to be authorized by an amended WIA that will consolidate the former Adult and Dislocated Worker Employment and Training Activities, together with the Employment Service.

The new consolidated adult program will include formula grants and a National Reserve, and will give States the ability to target resources where needed, facilitate coordination, and eliminate duplication in the provision of services to adults. With this request, we expect to be able to serve more participants than ever before.

Other Employment and Training Programs

The fiscal year 2004 budget includes $742 million for Other Employment and Training Programs. This includes $101.0 million, approximately the same as fiscal year 2003 levels, for new methods of providing workforce and related information through One Stop Career Centers using America's Labor Market Information System (ALMIS). In fiscal year 2004, a $500,000 initiative is included for the Wage

Record Interchange System (WRIS), in order to help States better track performance. Efforts to improve access to One Stop information and services include enhanced technology for serving individuals including those with disabilities.

In fiscal year 2004, an increase of $49.4 million will be provided as the first of a two-year investment to eliminate the 300,000 case backlog in the permanent Foreign Labor Certification program. In addition, funding will be provided in the Program Administration account to provide the Federal support necessary to address the backlog. To effectively address the situation, the backlog elimination will begin in fiscal year 2003 as DOL makes changes to the program that will prevent future backlogs by expediting certification and eliminating the state role in the processing of applications.

In fiscal year 2004, the budget includes $20 million for Work Incentive Grants, the same level provided in fiscal year 2003, to enhance the prospects of employment for individuals with disabilities. This effort is undertaken in conjunction with the Department's Office of Disability Employment Policy to increase the participation of individuals with disabilities in DOL programs and services. These grants augment the capacity of the One Stop Career Center system to deliver a full array of effective employment and training services to people with disabilities. Likewise, this effort will ensure that people with disabilities are better prepared to enter, re-enter, and remain in the workforce. In fiscal year 2004, the program will increase by about five percent the number of individuals placed in unsubsidized employment after program exit.

Office of Disability Employment Policy

The U.S. Department of Labor's Office of Disability Employment Policy's (ODEP's) mission is to provide leadership to increase employment opportunities for adults and youth with disabilities. ODEP is additionally tasked with serving as the lead agency in the Department's implementation of the employment-related goals of President George W. Bush's New Freedom Initiative. ODEP's fiscal year 2004 budget request of $47.3 and 65 FTE million will be used to increase marketplace demand for people with disabilities and support DOL's strategic goals through implementation of demonstration programs.

A primary area of emphasis will be on developing a reliable statistical measurement to determine the employment rate of people with disabilities because of the critical need for such data to inform policies and programs. In fiscal year 2004, ODEP and Bureau of Labor Statistics will pilot test disability employment rate questions through the Current Population Survey.

Veterans' Employment and Training Service

The Department's Veterans' Employment and Training Service (VETS) is requesting $219.9 million and 250 FTE to maximize employment opportunities for veterans, protect their employment rights and meet labor market demands with qualified veterans. VETS meets its primary responsibilities through the funding of state veterans employment and outreach specialists, referred to as Disabled Veterans' Outreach Program (DVOP) and Local Veterans' Employment Representative (LVER) positions.

As our Nation continues its war on terrorism, the activation of thousands of Reservists and National Guard members has made providing technical assistance to them and their employers one of the highest priorities for the Department. The Department, through VETS, administers USERRA—the Uniformed Services Employment and Reemployment Rights Act—a law that protects the jobs of these servicemembers at this critical time in our Nation's history.

The 2004 request funds the Homeless Veterans Reintegration Project at $19 million, an increase over the 2003 level. This program will provide employment and training assistance to homeless veterans, with expected job placements and retention of approximately 9,000 veterans.

WORKER PROTECTION

As we have recently discussed, Mr. Chairman, I remain deeply committed to enforcing the many laws that protect workers' safety and economic security. As demonstrated in the following initiatives, the Department's fiscal year 2004 budget was crafted to only strengthen that commitment.

EMPLOYMENT STANDARDS ADMINISTRATION

The Department's Employment Standards Administration (ESA) administers and enforces a variety of laws designed to enhance the welfare and protect the rights of American workers. The budget request to conduct these programs in fiscal year 2004 is $529.8 million and 4,360 FTE, down $38.4 million from fiscal year 2003.

This decrease is due largely to reduced funding for the Health and Human Services component of the Energy Employees Occupational Illness Compensation Program.

Office of Workers' Compensation Programs

As mentioned earlier, ESA's budget request includes a legislative proposal to finance the operations of the FECA program via a surcharge. Under this proposal, the direct budget authority for FECA program administration ($87.6 million) would be replaced with offsetting collections to be paid by Federal agencies based on their employees' pro rata share of workers' compensation benefits. Integration of the full cost of FECA benefits and administration in the appropriate agencies will boost Federal agencies' incentives for improving safety in their workplaces.

The Budget includes additional legislative proposals to promote benefit equity and to discourage unnecessary claims in the FECA program. Specifically, the budget proposes to amend FECA to move the waiting period before the continuation-of-pay period, conform the FECA benefits of future beneficiaries over the age of 65 to a benefit level typical to what they would receive under Federal retirement programs, and make a number of other changes to improve and update FECA.

Wage and Hour Division

The discretionary funding request for the Wage and Hour Division (WHD) is $5.4 million and 3 FTE higher than in fiscal year 2003. Wage and Hour will continue to use its multi-pronged approach of compliance assistance, partnerships, and enforcement to further its goals to promote high quality workplaces, a secure workforce, and customer satisfaction. The budget also includes $0.3 million and 3 FTE for enhancing compliance assistance to small and minority businesses. Wage and Hour's mandatory funding would decrease by an estimated $7.1 million from fiscal year 2003 due to the expiration of the American Competitiveness in the Twenty-first Century Act on September 30, 2003, and the corresponding reduction in fee revenues from the H–1B visa worker program.

WHD's budget includes a legislative proposal to increase civil penalties for child labor violations that cause the death or serious injury of a young worker. Our proposal would increase the maximum penalty from $11,000 to $50,000, for any type of child labor violation that leads to death or serious injury. We also propose to raise to $100,000 the maximum penalty for willful or repeat violations that lead to death or serious injury of a young worker. This proposal would provide the Department with the tools needed to address the most serious of child labor violations.

Office of Labor-Management Standards

The fiscal year 2004 budget request for the ESA's Office of Labor-Management Standards is $40.6 million and 372 FTE. OLMS enforces provisions of Federal law that require reports from unions and others and establishes certain standards for union democracy and financial integrity. OLMS conducts criminal investigations (primarily union funds embezzlement) and investigative audits of unions; conducts civil investigations (primarily concerning union officer elections); supervises remedial union officer elections, as required; administers statutory reporting requirements; and provides for public disclosure of filed reports.

The fiscal year 2004 budget request includes $5.3 million and an additional 75 FTE for enhanced outreach assistance activities and enforcement to ensure compliance with the Labor-Management Reporting and Disclosure Act. The budget request maintains resources for electronic filing and Internet public disclosure of the statutorily required reports. The budget also includes a proposal to authorize OLMS to impose Civil Money Penalties on unions, union officers, employers and consultants, and bonding companies that fail to file their required financial reports on a timely basis. The intent is to improve compliance, not penalize inadvertent lapses in filing reports.

Office of Federal Contract Compliance Programs

Total funding for OFCCP in fiscal year 2004 will increase by $2.0 million. OFCCP continues to ensure that federal contractors' hiring, promotion, and pay practices fully comply with federal equal employment opportunity laws. OFFCP targets and effectively remedies systemic discrimination in companies it monitors, extending the level playing field to large numbers of Americans working or seeking employment in thousands of establishments across the nation. OFCCP has recently put in place a case management process that makes key improvements to investigations and information management and continues to work closely with the Office of the Solicitor to bring legal expertise to bear on its investigations.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

The cornerstone of worker safety is the Occupational Safety and Health Administration (OSHA), which promulgates and enforces occupational safety and health standards and provides compliance assistance to employers and employees. OSHA also assists Federal agencies in establishing and maintaining occupational safety and health programs and provides funding for state-administered safety and health consultation programs. To meet its goals of reducing workplace injuries, illnesses, and fatalities, OSHA will focus on the most serious hazards and dangerous workplaces and expand compliance assistance opportunities. The fiscal year 2004 OSHA budget request is $450.0 million and 2,236 FTE.

Standards and Guidance

OSHA's standards and guidance activities provide for the development, promulgation, review and evaluation of occupational safety and health standards and nonregulatory products. In fiscal year 2004, OSHA will continue to base all standards on clear and sensible priorities and review existing rules to revise or eliminate obsolete and confusing standards or provisions. Consistent with the findings of the Administration's Performance Assessment Rating Tool (PART), OSHA will also conduct more rigorous cost-benefit analyses of its proposed standards. The fiscal year 2004 budget provides $14.5 million and 85 FTE for this activity.

Federal Enforcement

OSHA's Federal Enforcement activity increases compliance with workplace standards under the Occupational Safety and Health Act of 1970 through the on-site inspection of work places and by encouraging employers and employees to see safety and health as adding value to their businesses and their lives. OSHA will continue to target inspections based on the worst hazards and the most dangerous workplaces. In fiscal year 2004, the budget request for federal enforcement activity is $165.3 million and 1,581 FTE.

Compliance Assistance

The Agency will assist employers by continuing important programs like the Voluntary Protection Program and the State Consultation Program, which provides free, on-site compliance assistance for small employers. OSHA will also increase its efforts to reach vulnerable populations like non-English-speaking and contingent workers. The total request for compliance assistance activities is $124.0 million and 356 FTE.

MINE SAFETY AND HEALTH ADMINISTRATION

The Mine Safety and Health Administration (MSHA) protects the safety and health of the Nation's miners through enforcement of the Federal Mine Safety and Health Act of 1977. The fiscal year 2004 budget request for MSHA is $266.8 million and 2,334 FTE. MSHA created an additional budget activity for fiscal year 2004, Program Evaluation and Information Resources (PEIR). In the past, PEIR activities (including information technology and support of the Government Performance and Results Act) have been funded by drawing resources from each of MSHA's budget activities. The fiscal year 2004 Budget requests funds for these activities in a separate line (funding for PEIR activities is level with the fiscal year 2003 President's Budget).

Enforcement: Coal

The Coal Mine Safety and Health activity is responsible for ensuring the safety and health of the Nation's coal miners through special emphasis programs, compliance and training assistance, and periodic regular inspections and special investigations. The fiscal year 2004 request includes $113.4 million and 1,086 FTE for this activity, including $350 thousand for the cyclical replacement of health and safety sampling equipment.

Enforcement: Metal/Nonmetal

The fiscal year 2004 Budget includes $66.4 million and 622 FTE for Metal and Nonmetal Mine Safety and Health activities. These activities promote a healthful working environment in the Nation's metal and nonmetal mines and mills—and MSHA will accomplish this goal through compliance and training assistance, periodic regular inspections, and special investigations.

The request includes a $2.0 million and 20 FTE increase over the fiscal year 2003 request for health, safety, and compliance assistance to respond to the growth of the metal and nonmetal mining industry. The request also includes an increase of $200 thousand for the cyclical replacement of health and safety sampling equipment.

Educational Policy and Development

The fiscal year 2004 request includes $2.4 million and 21 FTE for a new Small Mine Office. The Office will help small mining operations by providing compliance assistance, guidance, and training; and reviewing regulations that impose undue burdens on small mines.

RETIREMENT SECURITY

President George W. Bush and I share the priority of ensuring increased retirement security—and the Department of Labor continues to lead the Nation's efforts in achieving such a goal.

EMPLOYEE BENEFITS SECURITY ADMINISTRATION

The name change that I mentioned earlier—from the Pension and Welfare Benefits Administration to the Employee Benefits Security Administration—does not alter and only strengthens the agency's mission: to protect the pension, health, and other benefits of participants in private sector employee benefit plans. In fiscal year 2004, the total request for EBSA is $128.6 million and 930 FTE. This is an increase of $12.3 million and 69 FTE over fiscal year 2003. The request includes $8.6 million and 69 FTE for the Department's Enhanced Retirement Security initiative which was designed to bolster compliance assistance and enforcement efforts related to pension and health fund protections.

In accomplishing its mission, EBSA directly affects the livelihood of over 150 million people who participate in Employee Retirement Income Security Act (ERISA)-covered plans, and protects the U.S. economy's single largest source of capital for investment: pension funds. EBSA will employ an integrated approach that encompasses programs for enforcement, compliance assistance, interpretive guidance, legislation, and benefits research to protect employee benefits and retirement security for our Nation's workers and retirees.

Enforcement and Participant Assistance

Mr. Chairman, since I appeared before this Subcommittee last year, EBSA has received 185,000 calls for assistance from Americans with questions about their retirement or other benefit plans. Many of those calls led to investigations. It is this activity that conducts criminal and civil investigations, performs reviews to ensure legal compliance, and further ensures compliance with applicable reporting requirements, as well as accounting, auditing, and actuarial standards. During 2002, as a result of EBSA's enforcement action, there were 134 criminal indictments issued, 4,925 civil investigations closed with monetary results of over $832 million. The 2004 request includes an initiative to enhance retirement security and nationwide enforcement coordination. In fiscal year 2004, the budget request for enforcement and participant assistance is $106.7 million and 800 FTE.

Policy and Compliance Assistance

This activity conducts policy, research, and legislative analyses on pension, health, and other employee benefit issues. Agency staff supporting this activity provide compliance assistance, especially to employers and plan officials, draft regulations and interpretations, and issue individual and class exemptions from regulations. In fiscal year 2004, the budget request for this activity totals $17.4 million and 108 FTE.

Executive Leadership Program

This activity provides leadership, policy direction, strategic planning, and administrative guidance in the management of employee benefits security programs. It provides analytical and administrative support for financial and human capital management and other administrative functions related to coordination and implementation of government-wide management initiatives. This activity also manages the technical program training for enforcement, policy, legislative and regulatory functions. In fiscal year 2004, the budget request for this activity totals $4.5 million and 22 FTE.

OFFICE OF INSPECTOR GENERAL

The Department's request for the Office of Inspector General is $67.1 million and 473 FTE for fiscal year 2004, an increase of $4.9 million and 20 FTE over fiscal year 2003.

Program Activities

The OIG budget includes resources for audit; program fraud; labor racketeering; special evaluations and inspections of program activities; and executive direction and management. The OIG performs audits of the Department's financial statements, programs, activities, and systems to determine whether information is reliable, controls are in place, resources are safeguarded, funds are expended in a manner consistent with laws and regulations and managed economically and efficiently, and desired program results are achieved.

The OIG also administers an investigative program to detect and deter fraud, waste, and abuse in Departmental programs and to identify and reduce labor racketeering and corruption in employee benefit plans, labor management relations, and internal union affairs.

The fiscal year 2004 request includes $2.5 million and 20 FTE to conduct a nationwide comprehensive initiative to combat labor racketeering relative to: pension and health care plan corruption and organized crime or corruption affecting industries and union leadership.

INTERNATIONAL LABOR AFFAIRS

As I referenced before, Mr. Chairman, the Department's budget request was developed with careful consideration of all the realities now facing our country. Development of the Bureau of International Labor Affairs (ILAB) budget was no exception. During the budget process, we had to set priorities to fund from our limited pool—and our Nation's current economic and employment conditions must be included more prominently in this equation. As a result, our fiscal year 2004 request for ILAB is $12.3 million and 60 FTE. This is a reduction of $135.0 million and 65 FTE from fiscal year 2003.

The fiscal year 2004 budget request refocuses ILAB on U.S. international policies and programs of greatest concern to American workers. ILAB will continue to coordinate the Department's global responsibilities in 2004 and to provide expert support for many of the Administration's international initiatives, including the promotion of core labor standards. The Bureau will continue to represent the U.S. Government at the International Labor Organization (ILO) and on the Employment, Labor and Social Affairs Committee of the Organization of Economic Development. The Bureau will also continue to fulfill the Department's responsibilities related to our participation in the development of U.S. trade policy and the negotiation of trade agreements.

The Department will continue to play a supportive role for other federal agencies in their efforts to further prevent and eliminate child labor and combating the spread of HIV/AIDS and will help to ensure that those priorities are addressed.

IMPLEMENTING THE PRESIDENT'S MANAGEMENT AGENDA

Before I close today, Mr. Chairman, I also want to highlight the Department's ongoing efforts to implement the President's Management Agenda—as well as to discuss our recent experiences with the Office of Management and Budget's Program Assessment Rating Tool (PART).

At my fiscal year 2003 appropriations hearing last year, I briefed the Subcommittee on the Department's progress in implementing the President's Management Agenda. As you know, Mr. Chairman, the President's Management Agenda is an aggressive strategy for improving the management of the Federal government with a focus on five government-wide areas: *Strategic Management of Human Capital; Competitive Sourcing; Improved Financial Performance; Expanded E-Government; and Budget and Performance Integration*. Further, DOL is also one of just five Cabinet agencies with Agenda responsibilities related to *Faith-based and Community-based initiatives.*

On a quarterly basis, the Office of Management and Budget has continued to rate the government's progress in implementing the President's Management Agenda on a "stoplight" color grading scale—and DOL continues to lead the way. As of the most recent OMB scorecard of December 31, 2002, DOL received a Yellow baseline rating for Human Capital with a Green progress score. For Competitive Sourcing, DOL received a Red baseline score with a Yellow progress rating. For Financial Management, DOL received a Yellow status score with a Green rating for progress—the exact same scores for E-Government, Budget and Performance Integration, and Faith-based and Community-based Initiatives. With that assessment, DOL continues to lead all Cabinet agencies in Status scores.

As OMB Director Mitchell E. Daniels, Jr., indicated at OMB's mid-session review last summer, "Labor has demonstrated a sustained commitment to implementation of the management agenda and is making good progress. A key component of the

department's success is its Management Review Board, which monitors progress by regularly reviewing department-wide reform implementation."

Program Assessment Rating Tool (PART)

Improving programs by focusing on results is an integral component of the President's budget and performance integration initiative. As such, the Administration rated effectiveness with its PART for approximately 20 percent of Federal programs. As part of this process, nine DOL programs were reviewed in calendar year 2002: Bureau of Labor Statistics; OSHA; EBSA (formerly PWBA); Office of Federal Contract Compliance Programs; FECA; Community Service Employment for Older Americans; Dislocated Worker Assistance; Trade Adjustment Assistance; and Youth Activities. Each program was rated on *Purpose, Planning, Management, and Results/Accountability* and the experience provided an invaluable management tool.

Highlights and results of the reviews, along with discussion of reforms we will make to address certain weaknesses identified using the PART, are included in the agency-specific sections of the Department's Congressional Budget Justification. We are already working with OMB on the programs to be reviewed in the next round of PART.

CONCLUSION

Mr. Chairman, this is an overview of what we have planned at the Department of Labor for fiscal year 2004.

I will be happy to answer any questions you may have on the Department's fiscal year 2004 budget request.

Senator SPECTER. Thank you very much, Secretary Chao.

Picking up on the issue of dislocated worker assistance, there are enormous problems in many industries, but using the steel industry as illustrative, as you are well aware, the American steel industry—before I proceed with the questioning, let me turn to Senator Murray for an opening statement.

OPENING STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Thank you very much, Mr. Chairman. Thank you for your statement, Madam Secretary, and I do have questions. Let me just say quickly that last Friday's March unemployment report brought more bad news for working men and women in this country of another 108,000 jobs lost nationwide, and that's on top of the nearly 2.4 million Americans who have lost their jobs since this administration took office. I'm really disappointed that the fiscal year 2004 budget request for the Department of Labor's Employment and Training Administration fails to recognize the workforce needs of this country and continues a pattern of short-changing and denying American workers access to the training and resources that they are increasingly requiring.

PREPARED STATEMENT

We're seeing tremendous suffering across the country in terms of economic hardship and record long-term joblessness, and I think we all know that studies have shown that 75 percent of the American workforce will need to be retrained to merely retain their jobs. In Washington State we have lost 80,000 good-paying jobs since September 11 in our aerospace airline and information technology industries, and there's not much future hope in those industries in the short term, and hopefully it will look better in the long term, but I think we really need to train a skilled workforce, and I am concerned that we are not meeting those needs.

Mr. Chairman, I do have a number of questions, and I appreciate the opportunity for opening remarks.

[The statement follows:]

PREPARED STATEMENT OF SENATOR PATTY MURRAY

Madame Secretary, thank you for your testimony.

Last Friday's March unemployment report brought more bad news for the working men and women of this country.

—Another 108,000 jobs were lost nationwide.

—That's on top of the nearly 2.4 million Americans who have lost their jobs since this Administration took office.

Unfortunately, the fiscal year 2004 budget request for the Department of Labor's Employment and Training Administration (ETA) fails to recognize the workforce needs of this country.

It also continues a pattern of shortchanging and denying American workers access to the training resources they need and that employers increasingly are requiring.

At a time when American workers are suffering continuing economic hardship and record long-term joblessness, the Bush budget proposes a cut of $678 million for Workforce Investment Act-funded programs.

Recent studies have shown that 75 percent of the American workforce will need to be retrained merely to retain their jobs.

In Washington we have lost 80,000 good-paying jobs since 9/11 in the aerospace, airline and information technology industries, with little prospect for near term rehires.

And while the U.S. economy's demand for a skilled workforce has increased dramatically over the last 20 years, federal funding to meet these needs has decreased by 25 percent.

I am concerned that we are not meeting the needs that exist.

DISLOCATED WORKER ASSISTANCE

Senator SPECTER. Thank you, Senator Murray. Senator Murray's point is in line with the question that I was about to propose, Madam Secretary.

The steel industry is only illustrative of one of the industries which is victimized by foreign subsidies and dumping, and the President personally intervened with the tariffs which were put into effect a little more than a year ago, and in Pennsylvania we are looking at very difficult times with dislocated workers, and it is not just a Pennsylvania problem, it is a national problem.

On our Steel Caucus meeting yesterday we had concerns expressed by Senators from West Virginia and Maryland and Minnesota. Are the funds which will be allocated for dislocated worker assistance sufficient, in your opinion?

Secretary CHAO. Let me make a statement at the outset that the number of people served will not change, and the $78 million——

Senator SPECTER. How can that be, with the cut of some $78 million?

Secretary CHAO. Because primarily, the workforce investment system still has approximately $1.7 billion in overhang. That is a figure that we have talked about in the past, but it seems as if every year there continues to be about $1.7 billion in overhang. Our commitment to helping dislocated workers cannot be questioned and during these particular times we are, of course, aware and want to help workers who are having a difficult time.

There is a whole array of assistance programs available to dislocated workers, and that includes a one-stop career center, that includes transitional assistance, of which there have been two temporary extensions of unemployment insurance benefits. There is trade adjustment assistance as well, so we believe the current figures, including the overlay, and also what we're trying to do is con-

solidate the three funding streams, dislocated workers, adult programs, and employment services under the Workforce Reinvestment Act through the consolidation of all the different programs, we believe that there will be actually more resources that will be more flexibly applied to where it is needed most, to workers who need it.

PENNSYLVANIA TAA FUNDING

Senator SPECTER. Madam Secretary, Pennsylvania has had insufficient funding in that line with the current larger allocation, and I am advised by State officials that Pennsylvania was just allocated another $10 million in fiscal year 2003 for training, and that those funds may be used both to enroll new trainees and pay for costs stemming from trainees already enrolled. Is that correct?

Secretary CHAO. We can take another look at that, but if I understood the question, apparently Pennsylvania has committed more money for training under this program than was available in both fiscal year 2002 and 2003. We have been working with the State on exploring various options to address this need, but the problem is that, absent specific statutory authority, obviously the funding available in a particular fiscal year could not be used for a prior year obligation, which is what we found.

Senator SPECTER. Well, would you take a look at that and see if there is some way that can be worked out to the satisfaction of the State officials?

Secretary CHAO. We will take another look.

Senator SPECTER. Pennsylvania has seen what has been termed to me a major mismatch between eligible recipients and Federal dollars. Aside from deferring new applications, what is the Labor Department's position as to how to allocate those funds?

Secretary CHAO. I am not totally informed on the specifics of your question, so let me go back and ask about that.

Senator SPECTER. All right. We would appreciate it if you would supplement your testimony here today when you have had a chance to review that.

[The information follows:]

PENNSYLVANIA TRADE ADJUSTMENT ASSISTANCE

The Trade Adjustment Assistance (TAA) program provides assistance to workers adversely impacted by trade. Workers certified by the Department of Labor under the TAA program are eligible for an array of services, including income support and job training. Once the Department of Labor certifies workers as eligible for TAA services, states are responsible for enrolling certified workers into reemployment services, which may include job training. Only training, income support, and out-of-area job search and relocation allowances may be funded by TAA; other reemployment services are provided through other WIA One-Stop delivery system partners.

Under the Trade Act of 2002, which amended the TAA program, the total resources available for training nationwide is capped at $220 million, an increase of $110 million available annually prior to the amendment. Because this is a "capped entitlement," individuals are entitled to training to the extent that funds are available. DOL distributes these funds to states upon review of information provided by states that includes estimates of the number of individuals who would require training and anticipated costs.

In recent years, the $110 million cap was reached well before the end of the fiscal year. In an effort both to better manage the limited funds available to serve trade-impacted workers and to better integrate the trade program services with the Workforce Investment Act (WIA) Dislocated Worker program services, DOL's Employment and Training Administration (ETA) issued guidance to states in September

2000 reminding them to coordinate with WIA Dislocated Worker programs to fund training for trade-impacted workers.

In February 2003, officials from the Commonwealth of Pennsylvania met with the Assistant Secretary of Labor for ETA, Emily Stover DeRocco, regarding $16 million owed by the State to providers for training invoices involving TAA participants that was in excess of the TAA training funds provided to the State for fiscal year 2002. Fiscal year 2003 TAA training funds could not be used since the costs were incurred prior to the fiscal year 2003 funds being appropriated.

Currently, ETA is working with the Commonwealth to address an additional shortfall in trade training funds for fiscal year 2003, which has the potential of impacting services to workers and payment to educational institutions and training providers. The deficit has raised serious concerns regarding the Commonwealth's operation of the TAA program and management of training funds.

ETA senior officials visited the Commonwealth and determined that the shortfall of funds in both years was caused by state employees approving and contracting for training for eligible workers without regard to the TAA training funds made available by ETA. State officials justified this because of what they believed to be the entitlement nature of the program. They indicated that, up until this recent problem, they did not concern themselves whether funding was available at the time of state obligation, as long as it was available when the bills had to be paid. The result was unpaid fiscal year 2002 bills and fiscal year 2003 training commitments that are not backed by Federal funds.

A letter was sent to the state requesting they review the $16 million in invoices from last year to identify how much was for training that began after July 1, 2002 that could be financed from currently available National Emergency Grant (NEG) monies and they determine the amount committed to workers for training begun or scheduled to begin after October 1, 2002 that is not presently covered by Federal TAA funding.

Also, subsequent to these findings, while awaiting the results of the Commonwealth's review, an additional $11.5 million in TAA funds for fiscal year 2003 were provided to cover the cost of new and future obligations incurred. State officials elected to use these monies to reduce the fiscal year 2003 shortfall and allow participants already in the program to continue their training.

The state did undertake a review of records as requested and responded on April 28th. They indicated that:

—$14.6 million in fiscal year 2002 training invoices has been paid for from non-Federal funds or are unpaid. The Commonwealth submitted a request for National Emergency Grant funds to cover these costs.

—There is an estimated shortfall this year of $16.2 million in fiscal year 2003 obligations for training already approved by the Commonwealth. Total obligations are $37.9 million compared with the Federal awards of $21.7 million for TAA training.

—The Commonwealth estimates that an additional $14.1 million needed to cover the costs of services for TAA applications currently pending.

Pennsylvania has been encouraged to use other available resources, including unexpended formula funds provided under WIA, to meet the needs of trade-impacted workers. The WIA funds that may be used to assist these workers are provided through dislocated worker and adult funding streams, and include funds reserved by the state for statewide activities and funds allocated to local workforce investment areas pursuant to substate funding formulas.

In addition, we are currently reviewing Pennsylvania's application for National Emergency Grant funds under WIA to satisfy fiscal year 2002 needs occurring after July 2002. We are also considering the $16.2 million and the $14.1 million current year's requirements along with needs identified by other states. As you know, sufficient funds will not be available this year to satisfy demand. A final decision on the amount that will be made available to Pennsylvania is pending analysis of the needs of all states.

Senator SPECTER. With 14 seconds left I am going to not pose another question which I couldn't get out in that length of time, and yield at this point to Senator Murray.

UI EXTENSION FOR AIRLINE WORKERS

Senator MURRAY. Thank you very much, Mr. Chairman.

Madam Secretary, let me start with the issue of the unemployment insurance benefits for airline workers. I was really dis-

appointed yesterday to see the President's opposition to a temporary extension of unemployment insurance benefits to our unemployed airline industry workers who have lost their jobs.

I was very heartened to see that 67 Republicans in the House joined all of the House Democrats to instruct the appropriations conference to help our workers, but if you can just tell us today, as Secretary of Labor, do you agree with the administration that we should provide billions of dollars in Federal aid to our industries without doing anything to support our workers who have played by the rules and have lost their jobs?

Secretary CHAO. The Department's total outlay last year, mandatory plus discretionary, was about $71 billion. The majority of that was for unemployment insurance. Included in that was $12 billion for our workforce investment system, which basically helps people train for new jobs. So, in essence, 97 percent of the Department of Labor's $71 billion budget is divided among unemployment insurance, transitional assistance, and training needs of workers, dislocated workers——

Senator MURRAY. Well, you understand that many of our airline workers have skills that are not transferable. They're Boeing machinists, they're airline workers who have very specific skills and training. We all, I think, expect the airline industry to get back on track hopefully in the near future rather than in the later future, but just saying, well, you get unemployment for a short amount of time and then we expect you to retrain for another industry, both leaves our airline industry in the future short of workers, but it also sets a very high expectation that somehow we're going to retrain thousands of people for jobs that don't exist.

The unemployment extension merely helps these people through a difficult time in our Nation's economy through tragic circumstances that have occurred in the airline industry beyond anybody's control.

Secretary CHAO. I agree with that. I didn't finish my answer. We do have also national emergency grants, of which I've given out, I believe, about $150 million to help specifically airline workers in this industry. We've had two extensions of unemployment insurance and right now potentially a worker can get up to 65 weeks of benefits.

We do have serious concerns about singling out one group of workers, and from an administrative point of view of how does that work——

Senator MURRAY. Well, let me go right to that. In fact, Mitch Daniels said in his letter, and I quote, to provide benefits for a specific industry would be unusual, unfair, and potentially harmful to our national unemployment system. Well, Madam Secretary, is it the administration's position that trade adjustment assistance, which does provide benefits to specific industries, is also unusual and unfair?

Secretary CHAO. Trade adjustment assistance was certainly expanded in the last TPA discussions.

Senator MURRAY. But it is a program that provides to specific industries, correct?

Secretary CHAO. It is for people who have been harmed by trade.

Senator MURRAY. To specific industries. So under the standard that an unemployment extension for airline industries is, and I quote: "unfair and potentially harmful because it provides benefits for a specific industry, and by the same standard, trade adjustment assistance would be"——

Secretary CHAO. Well, that's law by now, so I don't know whether it makes any sense to rehash that.

MIGRANT AND SEASONAL FARM WORKERS

Senator MURRAY. Okay. Well, let me ask a different question.

It appears that the Department no longer believes that a national program for migrant and seasonal farm workers is needed. How are we going to avoid burdening our Governors and local one-stops with the responsibility of trying to serve workers who may work and reside in their States for brief periods during this time of huge and growing State deficits?

Secretary CHAO. The original intent of this program for migrant workers was to help them train for new skills so that they can get out of this low-paying and very difficult work. As it has turned out, based on experience, we have found that this program was used much more for income support.

If indeed these resources are to be used to supplement income and to be used as income support, there are other programs which this can be melded into.

Senator MURRAY. Such as?

Secretary CHAO. Well, I think they should be linked into the workforce investment system overall, and other available programs.

Senator MURRAY. There isn't enough money in the workforce system now. If we say to all seasonal workers and migrant workers, we're now expecting you to be taken care of under that program, too, we are adding a huge burden to that.

Secretary CHAO. Well, the workforce investment system right now is underutilized, first of all, and second, the migrant workers, segregating them into a specific area will not be helpful to fully integrating them into local communities.

GAO REPORT REGARDING WIA SPENDING

Senator MURRAY. Well, let me go back to that, because I'm confused. You keep arguing that employment and training services can be accomplished without impacting service delivery because of carryover funds in the WIA formula programs, but the GAO conducted an investigation and found the administration's argument inaccurate, and it said, and I quote: "our analysis of Labor's data shows that States are rapidly spending their funds."

In fact, nationwide, States have spent 90 percent within 2 years, even though the law allows 3 years to spend the money, and, in fact, my State was to have spent 98 percent of their formula funding in 2001, so I don't understand how we keep hearing you say that. I mean, I have the GAO report here.

Secretary CHAO. May I answer that?

Senator MURRAY. Yes.

Senator SPECTER. She's correct, you may answer, even though the red light is on.

Secretary CHAO. We obviously disagree with the GAO report. I think we all need to take a look at the balances outstanding, and clearly, in every single State there are positive balances. This balance is not only for 1 year but, in fact, it's for every year. So there is a disagreement about whether to use obligations versus expenditures, and there is a disagreement as to how much the overlay means, but when it continues year after year, I think that needs to be looked at.

But let me also say the total level of funding remains the same in our proposal. Primarily, we are consolidating these various different programmatic streams, because it's very confusing for the recipient, to have to go to all these different programs. What we want to do through Workforce Investment Act reauthorization, which we discussed before, is to make the program simpler, give the States more flexibility so that there is more leeway with which to allocate resources to these various different groups of people who need assistance.

Senator MURRAY. Mr. Chairman, my time is up, but I would like permission to submit my other questions for the record.

Senator SPECTER. By all means, Senator Murray, they will be submitted.

The ladies and gentlemen who are standing in the rear can find seats here along the side, or if you're intending a career in journalism you can sit at that table.

If you plan to be Senate staffers you can sit in the chairs behind the podium. If you plan to be Senators, you may sit in the chairs at the dias here.

Now I turn to my distinguished ranking member, Senator Tom Harkin, Democrat of Iowa.

Senator HARKIN. Thank you very much, Mr. Chairman. Sorry I'm a little late.

Senator SPECTER. It looks like the journalists have it, Tom. That table is filled.

Senator HARKIN. A wise choice.

INTERNATIONAL CHILD LABOR

Madam Secretary, I hope your staff has given you all the stuff. I'm sure they know what I'm going to talk about.

Secretary CHAO. I hope so, too.

Senator HARKIN. Child labor. Child labor, child labor——

Secretary CHAO. Thank you.

Senator HARKIN [continuing]. Child labor. Let me repeat for you what you said to me last year, if I can get my proper page out here, in a hearing, since you zeroed out all these things in the budget. You said—this is your words. So please be assured that we are not differing at all in terms of the goal. This is on the international program for the elimination of child labor, ILAB. We want to work with you on this. The issue is how best to do so and how we can work, and how ILAB can absorb all this money in such a short period of time, but the commitment, I assure you, is absolutely there. We look forward to working with you on that. Well, I will work with you on it.

Well, here we are. Your budget justification touts the fact that ILAB child labor programs targeted more than 103,000 at-risk chil-

dren in fiscal year 2002, exceeded its goal of targeting 90,000 children. Your own document, I quote, says: "13 countries established a total of 15 new action plans, demonstrating concrete commitments at the highest levels of local and national Government to eliminate child labor." Well, that's pretty good news. That's good news.

Well, now your budget eliminates all funding aimed at preventing exploitive child labor. The U.S. contribution to IPEC is zeroed out. The money to provide bilateral assistance to other countries, to promote access to basic education for child labor, a critically important part of this, is zeroed out. Now, tell me about your absolute commitment.

Secretary CHAO. Well, this request doesn't mean that the Department will play no role in supporting international efforts to prevent and also eliminate, child labor. Rather, we hope to use the interagency process to make sure the Government agencies active in international affairs address these priorities on an ongoing basis.

Ongoing ILAB projects will also not come to an abrupt halt. There is still funding remaining for 2-year moneys appropriated in fiscal year 2003. I think the overall goal is that our technical assistance projects will continue to operate as ILAB transitions into a more policy-oriented role rather than a grant-making one.

Senator HARKIN. Well, I'm not certain I know what all that means. I don't know what that means, Secretary Chao. To me, that's gobbledygook written by somebody back there in your Department, but it's some kind of a gobbledygook justification for zeroing this out. I mean, I'm looking at the figures. This says something to me. Total ILAB, $12.2 million. Do you know what we enacted last year?

Secretary CHAO. $147 million.

Senator HARKIN. $148 million. Senator Specter and I and others on a bipartisan basis enacted that, and you're telling me with $12 million you're going to continue the program, and that it's a total commitment.

Now, I don't know. I mean, I take you at your word, but I don't know. I don't know if this is OMB, or where this is coming from, but somebody's got their priorities terribly wrong, whoever came up with this. I mean, your own Department has shown that this is working. It's doing great stuff around the world.

I mean, you know, I realize—I look around and I see all what we are doing now, and our military is strong, and we're very powerful, but I've got to tell you, this means more to people in third world countries than anything else we're doing, getting those kids out of those jobs, getting them a basic education, and when it has the imprint of the United States on it, that means something, and it's happening in countries that we're going to have some problems with in the next few years, and for $148 million it seems to me that that's a mere pittance of what we're spending in other areas.

Well, Madam Secretary, I'm just really disappointed. I'm just really disappointed in this, and I hope that we can come up with the money. It's a tight year, and obviously we have to take our cues—I know the burden the chairman labors under. I've had that position myself. I know what it's like to labor under a position where the budget comes out, and the administration, especially if

it's one of your own party, isn't supporting something like this. It's very tough.

But I hope that you'll take back to OMB and to the White House that they're making a terrible mistake here, a terrible mistake. It just paints the United States once again as uninterested in helping kids around the world break the bonds of child labor.

Oh, yeah, we'll say nice things about it. Oh yeah, we're opposed to child labor, we don't like that, but when it comes to putting the money out and doing things that have proven effective by your own Department's standards, and then we cut it back, I think it paints a very bad picture of the United States in many, many parts of the world, and it's dooming a lot of kids to continue that cycle, that generational cycle of poverty, no education, so they're condemned to living a life of menial work, and then their kids, the same thing.

Well, I've said enough. I don't need to say any more, but I'm really disappointed in this.

Thank you.

MINE SAFETY AND HEALTH

Senator SPECTER. Thank you, Senator Harkin.

Madam Secretary, turning to the issue of mine safety, last October 21 this subcommittee held a hearing in Johnstown on the mine disaster at Quecreek, and in this year's budget we have $10 million allocated for digitizing mine maps. There was a problem with mine maps. The 2004 budget proposes an overall increase of 35 staff, but coal mine inspectors will not be increased.

Would you take a look at that and respond to the subcommittee in writing as to your best efforts to try to increase coal mine inspectors within the allocated funds, and would you also include a specification as to how you're going to use the $10 million for mine mapping activities, and when you propose to start on that? Since we were so late in getting a budget to you, you understandably wouldn't be in a position to tell us what you've done in the short interval, but if you would respond in writing——

Secretary CHAO. I will do so.

Senator SPECTER [continuing]. The subcommittee would appreciate that.

Secretary CHAO. Are you interested in getting some of the answers now, or would you like me to submit it in writing?

Senator SPECTER. What was that?

Secretary CHAO. Would you like some of the answers now, or would you like me to submit it in writing?

Senator SPECTER. I would like it in writing——

Secretary CHAO. Okay.

Senator SPECTER [continuing]. Because there are so many other priority subjects to be covered.

[The information follows:]

PROPOSED PLAN OF THE MINE SAFETY AND HEALTH ADMINISTRATION DISTRIBUTING FISCAL YEAR 2003 APPROPRIATIONS OF $10 MILLION FOR DIGITIZING MINE MAPS AND DEVELOPING TECHNOLOGY TO DETECT MINE VOIDS

As defined in the House/Senate Conference agreement, $10,000,000 was appropriated to MSHA "for digitizing mine maps and developing technologies to detect mine voids, through contracts, grants, or other arrangements, to remain available until expended." Due to the across-the-board budget rescission of .0065, the $10 mil-

lion is decreased by $65,000 to $9.935 million. The purpose of this undertaking is to mitigate potential hazards to miners resulting from water and gas inundations when mining in close proximity to abandoned mines.

MSHA proposes a 3-year disbursement plan to allocate the funds in accordance with congressional intent. The funds will be allocated in two areas. The first area will be for use by state mining agencies for "Digitizing Mine Maps." The second area will be funding "Applied Technology Demonstration Projects." These projects will demonstrate the viability of new or existing mining technology to identify abandoned mines (voids) and the extent of their workings.

MSHA proposes allocating 40 percent of the funds to mine mapping and 60 percent to void detection. MSHA will disburse to the states $2,000,000 the first year and $1,000,000 each of the following years for mine mapping. MSHA will disburse funds for Applied Technology Demonstration Projects on a periodic payment schedule over the life of the project.

Digitization of Mine Maps.—It is estimated there are approximately 150,000 abandoned mines in Kentucky, 15,000 in Pennsylvania, 6,000 in Virginia, and 100,000 in West Virginia. In February 2003, MSHA held a meeting with representatives of various Federal agencies with responsibility for mine maps. Representatives from the Department of Interior's United States Geologic Survey (USGS), Bureau of Land Management (BLM) and Office of Surface Mining (OSM) attended. MSHA found that OSM provides funding to the states for hardware and software purchases for digital mine mapping efforts. OSM is currently surveying the states to determine the number of abandoned mines, the extent of state map digitizing efforts, and details of the current status of that state's work. When MSHA receives the OSM survey results, the Agency will be able to identify states' needs and develop the specific criteria to be used to distribute the funds. MSHA and OSM have discussed the possible transfer of funds to OSM through an Interagency Agreement. OSM could distribute the funds along with funds they are already providing the states. As an alternative, MSHA may enter into contracts directly with the states.

Once all known maps are digitized, detailed information on abandoned mines will be available prior to mining. This will reduce the likelihood of mining into abandoned mines.

Applied Technology Demonstration Projects.—MSHA is aware of technologies that exist which show potential for detecting in-seam voids (detection of abandoned mines). We expect companies that specialize in some of these technologies to submit proposals for demonstration projects. Also, experts at universities and contractors for government agencies such as DOE and DOD may submit proposals. Some promising technologies that MSHA hopes to have contractors explore:

Subterranean Robots Demonstration Project.—Field Robotics represents proven technology. Robots can be used to physically enter, provide a visual image, and ultimately map abandoned underground mines that are not safe for human entry. In addition to the drive components and navigational system, robots can be equipped with sonar and laser scanners to measure and map fine details. The primary challenge is to develop mine-worthy robots that can be adapted to the aggressive and diverse mine environment, with sufficient mobility through debris, mud, water, and dry conditions. For example, researchers from the Robotics Institute at Carnegie Mellon University have already field-tested a mine-mapping robot, that traversed more than one mile in a mine in 3.5 hours. They are interested in developing borehole robots for both wet and dry coal mine conditions.

Ground Penetrating Radar (GPR) Sensors Demonstration Project.—Technology located underground on the working section may be available that can "sense" at least 22 feet into a coalbed to detect air or water-filled voids. The system involves a radar device encased within an MSHA-approved flameproof enclosure. The device could be periodically moved to the mine face and readings taken to determine the presence of and distance to either an air- or water-filled void, differentiate between the two, and provide the operator with a graphical display of the conditions.

Seismic Reflection Demonstration Project.—Seismic technology may be a method to identify abandoned mines. It can be either a surface- or underground-based device. Surface-based devices are used to identify coal bed methane for the oil and gas industry. This technology may be adapted to detect air- or water-filled voids. Since this type of testing is widespread in the oil/natural gas industry, there would likely be a number of companies capable of demonstrating this technology under a variety of field conditions.

In-seam seismic techniques have proven successful in some situations. Possible projects may be to use the continuous mining machine cutting drum as a seismic source, and automating the system to cause a fail-safe shut-down of equipment before cutting-through into an abandoned mine. Borehole seismic tomography projects

to demonstrate mine-to-borehole and borehole-to-borehole seismic methods may also be viable.

Long-Hole Directional Drilling Demonstration Project.—This technology would demonstrate whether directional long-hole drilling could be used to establish the minimum width of an outcrop barrier by drilling a hole that is parallel to, but offset from, the outcrop line of a coal seam. This could identify the intact width of outcrop barriers in cases where an impoundment overlies the outcrop of a seam that is being actively mined. It would require investigating the capabilities, limitations, and safety considerations inherent to using this system underground. Further development and use of borehole geophysical instruments could enhance the capabilities of long-hole drilling immensely by accurately assessing the trajectory of an undulating coal seam. Adding geophysical logging tools would also allow the driller to determine the distance that the drill string is from the mine void, whether the void contains air or water, the thickness of the coal seam, and any geologic anomalies that could impact inundation risk.

FILLING COAL MINE INSPECTORS POSITIONS

Filling vacant coal mine inspector positions can be a lengthy process, especially due to the requirements for background investigations and medical examinations. MSHA has taken steps to compress that process where possible. MSHA Assistant Secretary Dave Lauriski has initiated an aggressive recruiting effort to fill vacant coal mine inspector positions. He has established specific deadlines for filling positions.

MSHA has traditionally filled inspector positions by selecting applicants for consideration from standing registers of eligible candidates. To increase the pool of applicants, MSHA is now supplementing this process by posting individual vacancy announcements for specific geographical locations. This will allow individuals whose names are not on the standing registers to apply and be considered for a particular vacancy. The Agency is placing vacancy announcement notices on the web site of the Department of Labor and the USAJOBS web site of the Office of Personnel Management. State employment offices access the USAJOBS site and make the announcements available. MSHA staff are recruiting applicants at job fairs and at universities. This aggressive recruitment effort will enable the Agency to fill vacant positions in a more timely manner.

ERGONOMICS

Senator SPECTER. Turning to the issue of ergonomics, last year in April you proposed to reduce ergonomic injuries through voluntary guidelines, but to have enforcement under OSHA's general duty clause. OSHA, I am informed, has conducted more than 400 nursing home inspections in the last year and 103 ergonomics inspections were conducted in industries other than nursing homes. Would you give us the detail in writing as to where those 103 ergonomic inspections were conducted, and give us your evaluation as to whether you think the inspections are adequate, and advise us as to how much funding is being directed to those inspections to evaluate voluntary compliances?

Secretary CHAO. We will do so.

Senator SPECTER. And the general duty inspections have disclosed, have resulted in citations, four citations, and we are advised that others are reportedly in progress. The subcommittee would like to know what has happened with those citations, what others are in progress, and whether you consider four citations to be adequate on some 491 inspections which have been conducted.

Secretary CHAO. Well, musculoskeletal injuries have actually dropped 10 percent last year. We will provide the answer, of course. In trying to work on these four general duty clauses, we want to make sure that they are effective. We talked a lot of target inspections and how we wanted to make sure that we are able to

use leverage and utilize most effectively this general duty clause to get at the bad actors. We will ensure that there is some kind of further followup with relation to our four-prong strategy of our ergonomics plan.

Senator SPECTER. Well, we need to evaluate what your voluntary guidelines are producing. Off-hand, on the surface, it would appear to me that 103 ergonomic inspections in all other industries beyond nursing homes is a small number. Do you think that's adequate? Tell me now.

Secretary CHAO. We're very committed, as I mentioned before, to ensuring that ergonomic injuries decline, and last year's results facts speak for themselves. There's been a 10-percent decrease in ergonomic——

Senator SPECTER. Madam Secretary, I understand your commitment.

Secretary CHAO. Yes.

Senator SPECTER. My question is, is that a sufficient number of inspections for all industries other than nursing homes?

Secretary CHAO. We conduct 37,000 inspections, so in addition to other inspections, these are just totally focused on other industries.

Senator SPECTER. You conduct how many inspections?

Secretary CHAO. 37,000.

Senator SPECTER. My red light is on, and I'm going to observe the time limit which I'm asking everyone else to do.

Secretary CHAO. I will submit the answer.

Senator SPECTER. So if you would respond——

Secretary CHAO. I will.

Senator SPECTER [continuing]. In writing, we would appreciate it.

[The information follows:]

OSHA has targeted ergonomic inspections to industries with high rates of musculoskeletal disorders. Inspections under OSHA's National Emphasis Program (NEP) for Nursing and Personal Care Facilities, which focuses on patient-handling hazards, began on September 17, 2002. Since this time, OSHA has completed over 469 inspections in Nursing Homes under the Nursing Home NEP. Over the past winter, Regional and Area Offices implemented Local Emphasis Programs (LEPs) to address ergonomics in several other industries with high rates of musculoskeletal disorders.

In all, OSHA has assessed ergonomic conditions in 675 of the inspections opened between January 1, 2002 and March 31, 2003. These inspections include 469 in nursing and personal care facilities pursuant to the NEP; 106 in other industries as a result of SST inspections or complaints or referrals; and 50 inspections in industries targeted by ergonomic-related Local and Regional Emphasis Programs.

Inspection type	Time period	Number of inspections
Nursing Homes under the Nursing Home NEP	September 17, 2002 through March 31, 2003	469
Ergonomic Related—Non-Nursing Homes	January 1, 2002 through March 31, 2003	106
LEPs—Ergonomic Related	December 15, 2002 through March 31, 2003	50

The resources utilized to address ergonomics in both the fiscal year 2003 and fiscal year 2004 budget request are contained within all of OSHA's budget activities and are not separately identified or earmarked to address ergonomics or any other specific issue. Rather, the comprehensive approach to ergonomics involves focused activity by the entire agency in addressing the four prongs of the ergonomics policy: industry specific and task-specific guidelines, strong enforcement, outreach and assistance, and research.

As part of our four-pronged approach to ergonomics, OSHA is increasing its outreach and assistance efforts through its Ergonomics Webpage, cooperative programs, and other means.

OSHA's cooperative programs are achieving tangible results and are an integral part of our strategy to reduce workplace ergonomics hazards. OSHA recently entered into a national partnership with the U.S. Postal Service, the National Postal Mail Handlers Union and the American Postal Workers Union to address ergonomic hazards in postal facilities. In addition 15 of OSHA's National Alliances focus on ergonomics.

The level of interest in OSHA's initiatives and activities is demonstrated by participation in stakeholder meetings, visitors to our ergonomics web page, inquiries regarding enforcement policy, alliances and partnerships which affect ergonomics, requests for consultation and compliance assistance, and interest in the work of the National Advisory Committee for Ergonomics.

OSHA has committed to achieving significant overall reductions in workplace injury and illness rates. Reducing the number of injuries due to ergonomic hazards is an important part of meeting these goals.

Senator SPECTER. We have been joined by the distinguished former chairman of the Appropriations Committee, former president pro tempore, current ranking member of the full committee.

Senator BYRD. Thank you, Mr. Chairman.

We've had great success in sending a man to the moon and bringing him home to earth again, but we've never been able to perfect a good public address system.

MINE SAFETY AND HEALTH INSPECTORS IN WEST VIRGINIA

Can you hear me, Madam Secretary?

Secretary CHAO. I sure can, thank you.

Senator BYRD. Last January, an air shaft explosion killed three workers at the McElroy mine in Cameron, West Virginia. According to news reports, MSHA's District 3 office, where the McElroy explosion occurred, was extremely short-staffed. One news journal reported that, according to MSHA records, between December 2001 and December 2003, when the McElroy mine should have had six surface inspections, it had been inspected only once. No underground inspections were performed. The MSHA district manager reportedly requested additional inspectors and resources, but was granted less than half of his request because of personnel shortages.

Now I read that the President has proposed to cut MSHA's budget for coal enforcement activities below the $119 million appropriated for fiscal year 2003 to $113.4 million in fiscal year 2004. Coal miners toil every day in an occupation where an accident can mean loss of a life. They trust that MSHA will do all that it can to reduce the risk of accidents. Why are there not enough inspectors in MSHA's District 3 office to conduct adequate safety inspections, and is insufficient staffing a problem that is widespread through MSHA?

Secretary CHAO. The simple answer is no, it is not. In fact, if you look at the last year's results there has been a 30 percent increase in site visits, 83,000, there's been a 21 percent decrease in fatalities, 11 percent decrease in injuries, 8 percent increase in citations and orders at coal mines.

The number of mines and inspection completion rates for coal mines actually stayed, from about—a 99 percent completion rate, which is an impressive number. The issue is that the number of coal mines has actually decreased since 1997, the last 5 years alone. There were 2,600 coal mines in 1997. Today, there are only 2,000, and yet the number of inspectors have remained the same.

In the next year we expect to add 35 increased coal miner inspectors, 20 metal/nonmetal inspectors, and another 21 to make sure the small mine companies and operators are abiding by the law as well, and we want to help them understand what their responsibilities, and also help the employees, the workers understand what their rights are. So we in fact have about a 76 increase, new inspectors coming on board.

Senator BYRD. The UMWA wrote to me just a few days ago to apprise me of their concerns with regard to the number of MSHA inspections at our Nation's mines. The UMWA wrote that the MSHA District 3 office in Morgantown, West Virginia is bringing MSHA inspectors in from Pennsylvania and housing them in hotels to inspect District 3 mines in an attempt to keep up with MSHA's mandatory inspection requirements.

The UMWA cited a series of accidents that have occurred since last April in Kentucky, Illinois, Pennsylvania, and West Virginia. Last year's Quecreek accident alone endangered 18 miners. Had it swung the other way, which it easily could have, fatalities would have increased last year greatly, rather than decreased, so are we really giving MSHA all of the resources it needs to protect our miners from these kinds of accidents?

Secretary CHAO. We actually have increased MSHA's budget, so we believe yes. With the problem specifically with district number 3, that is a district that we have heard complaints about. The UMWA has been very concerned about that. Many of the steps, actually, that we've taken are actually in response to what they want.

Senator BYRD. Would you say that again? Would you say that again, what you just said?

MSHA DISTRICT 3 REGIONAL OFFICE IN WEST VIRGINIA

Secretary CHAO. District number 3 is a district that we know has had some complaints, and a lot of the complaints circled around personnel. We have made certain changes. Certain other allegations of personnel changes were not true. That's the district that again——

Senator BYRD. What allegations were not true?

Secretary CHAO. That certain managers were moved out. That is not true. The one manager that was moved out, the UMWA wanted the person moved out, so we've done that.

Senator BYRD. If there are reports that mines are not being inspected because of the shortage of personnel, how can you be sure about whether more MSHA inspectors are needed?

Secretary CHAO. With the inspection completion rate of 99 percent, there is only 1 percent that we can do better. We will certainly try to do that, but I think there are very few other endeavors in which you have a 99 percent completion rate. As I mentioned, while there are injuries and fatalities, which are intolerable, the overall record in terms of safety has actually improved quite a bit in the last year.

As I mentioned, we have had a 30 percent increase in inspection citations, and an 8 percent increase in orders. There have been decreases in fatality rates. In fact, the mining industry had one of its best years in the last year, in terms of safety. The number of inju-

ries dropped as well, and we are adding 76 more inspectors in this coming year.

RETIREMENT OF MSHA INSPECTORS

Senator BYRD. Madam Secretary, you have been lucky. As I indicated earlier, if last year's Quecreek accident had swung the other way, which it easily could have, fatalities would have greatly increased last year rather than decreased.

The United Mine Workers of America also raised concerns about the upcoming retirement of a number of MSHA inspectors. MSHA has said that it takes 1 to 2 years to train a new inspector. When you tell this subcommittee that the President's budget request for MSHA is adequate to hire inspectors, are you considering these impending retirements?

Secretary CHAO. Yes, we are. It does take a great deal of skill to manage the personnel resources that are available within the Department. Part of the issue also is that it is difficult sometimes to find people at the locations in which they are needed. Many times an inspector, or a potential inspector, would not want to move to another part of the country or region in which he or she is not familiar.

There have been attempts in the past to accelerate the responsibilities, the time in which it would take for an inspector to get into their inspection activities, and we don't approve of that either. We want to make sure that the mine inspectors are doing their job, that they're highly qualified and highly skilled, because as you said, we want to make sure the miners get home every night, but we view this responsibility very seriously.

Senator BYRD. I helped to craft the 1969 and 1977 Federal Mine Health and Safety Acts. I did so with the belief that we need strong mine safety standards that are enforced through frequent inspections, and further, that appropriate stiff penalties be imposed on those mine operators who wilfully violate the law and endanger the lives of the Nation's coal miners, so I am concerned about this administration.

What I'm concerned about is how this administration is reconciling MSHA's enforcement and compliance assistance roles. I see resources and personnel being shifted away from enforcement activities. I hear about the failure to cite safety violations. I hear that violations at our site have sometimes languished unchecked for months. I hear about personnel transfers because of complaints from coal mine operators to administration officials that MSHA enforcement actions are too tough.

MSHA is not a consulting firm. It was created to enforce our mine safety laws. Just as the FBI should not act as a consultant to criminals, MSHA should not act as a consultant to coal companies that wilfully violate the law. Why should MSHA be distracted from its principal responsibility of enforcing our mine safety laws and protecting our miners so that it can act as an advisor to coal companies that break the law?

Secretary CHAO. Well, first of all, those allegations that you have cited earlier in your statement are just not true.

Senator BYRD. Which allegations are not true?

Secretary CHAO. The coal operator who claimed that he moved certain personnel out. There is a very comprehensive answer to those spurious charges by Dave Lauriski, the Administrator of MSHA, that is in the Courier-Journal, and I will send that over if you have not seen it already.

Second of all, I think some people would take exception to the——

Senator BYRD. You will send that over, you say?

Secretary CHAO. Sorry?

Senator BYRD. You say you will send that over?

Secretary CHAO. I will do so, yes.

Senator BYRD. How soon will I see that?

Secretary CHAO. Just to make sure, I will send it over.

[The information follows:]

[From the Courier-Journal, Louisville, KY, March 16, 2003]

MSHA SAYS: "PROTECTING MINERS COMES FIRST"

(By Dave Lauriski, Special to The Courier-Journal)

The writer is assistant secretary of Labor for mine safety and health.

Over the last two years, the Bush administration has instituted a culture of accountability and performance in the enforcement programs that protect miners' lives—and the clear result is that miners are safer than ever before. But you wouldn't know it from the biased and baseless screeds The Courier-Journal is negligently posting on its opinion pages today.

Here are the facts:

—We conducted 87,957 mine inspection and en-forcement events in 2002—an increase of 30 percent since the previous administration.

—Over the last two years, citations and enforcement orders issued against coal mine operators passed the 125,000 mark—up 8 percent since the last administration.

—During that same period, we assessed mine operators with $27.3 million in civil penalties—an 11 percent jump.

Here are the results:

—Because of our no-compromise enforcement policy, fatal injuries at mines have declined to their lowest point in history.

—Coal mine injury rates have fallen by nearly 10 percent since we came into office, and are lower than at any time in the last 20 years.

—The only way to achieve results like these is to insist that protecting miners comes first—not protecting the bureaucracy, the industry or individual coal operators.

For these reasons, it is both stunning and sad to see Cecil Roberts, president of the United Mine Workers of America, sign his name to an irresponsible opinion piece that accuses the administration of putting politics ahead of miners' safety. Cecil is a decent man, and we have worked well with him on mine safety issues. But the arguments he makes—mostly cribbed from a West Virginia radio story—are flatly contradicted by the facts and even conflict with the views expressed by senior leaders in his own organization.

Roberts says he has grounds to be "suspicious" of the reassignment of MSHA's District 3 manager, insinuating that it was payback for enforcement actions against Robert Murray, a politically active coal operator. That's odd, because the organization that Roberts runs has complained bitterly about the District 3 manager and demanded that we take action.

Roberts' own safety director wrote to MSHA, "A number of complaints have been filed with the MSHA District 3 and Arlington offices. . . . As you know, miners became so fed up with the actions of the Agency and particularly the MSHA District 3 manager that they staged a protest at an MSHA meeting two months ago." The UMWA has accused the District 3 management of "tolerating hazardous conditions," turning "a blind eye" to violations and stopping MSHA inspectors "from issuing enforcement actions." Richard Eddy, president of UMWA District 31, also wrote to complain about decisions made by MSHA's District 3 manager. Eddy urged me to "take whatever actions you deem necessary."

Seemingly unaware of all this, Roberts blames the reassignment of the District 3 manager on "threats" allegedly made by coal operator Robert Murray. As we say in the country, that dog won't hunt.

Roberts also alleges that I met with Murray in April 2002 and that "the result of those meetings was the sudden reassignment of District 2 officials Kevin Stricklin . . . and Tom Light, whose reassignment Murray [had] bragged about. . . ." None of that is remotely true. There was no such April meeting. And Kevin Stricklin is still with District 2; the only "reassignment" he had was a leadership development rotation as assistant to the coal administrator, one of the most highly responsible positions at MSHA. The same goes for Tom Light, who is also still with District 2 and, far from being punished, was promoted to the second-ranking job in the regional office.

Finally, Roberts claims that Murray asserted his political influence to threaten two other MSHA enforcement officials in the District 3 office. Regardless of any threats made by anyone, I'm the one who is responsible for all personnel decisions in MSHA—and both of those officials are still at their posts.

The only MSHA official mentioned by Roberts who was permanently transferred is the former manager of District 3. But Roberts' own safety director and local union president are on record insisting that action be taken against him. So why is Roberts cooking up conspiracy theories against this administration? I refuse to believe that Roberts would play politics with miners' safety—even though he has falsely accused MSHA of doing the same. Roberts appears to be the victim of overzealous staff who failed to do good research and left him out to dry.

The truth is that the Bush administration and MSHA take miners' safety very seriously. One of the first decisions the new administration made was to fully defend and enforce the Black Lung Program regulations that were issued in the waning days of the previous administration. Mine operators like Robert Murray strongly urged the administration to back down. Instead, we took the side of protecting miners' health—a decision strongly endorsed by The Courier-Journal and Cecil Roberts' UMWA.

Today, we are setting new records in enforcement and reduced injury and fatality rates. But we are not resting on these achievements, because our job is to bring miners home to their families, safe and sound. In our budget for next year, we proposed tougher penalties for mine safety violations and added funding to hire 55 more mine inspectors. And we continue to pursue a major enforcement case against the Ohio Valley Coal Company—owned by none other than Robert Murray.

The accusation that anyone in this administration assigns a higher value to political contributions than to miners' health and safety is insulting and clearly disproved by the facts. It is uncharacteristic of Roberts to make such irresponsible attacks. However, placing these baseless claims on the opinion page does not absolve The Courier-Journal from the responsibility of doing some basic fact checking before printing them.

Senator BYRD. It won't be like your response to my January letter, will it, the response that just came yesterday?

Secretary CHAO. What response?

Senator BYRD. The response to my January letter.

Secretary CHAO. I'm not—you're saying it came in too late, is that what——

Senator BYRD. Pardon me?

Secretary CHAO. Are you saying that it came in too late?

Senator BYRD. Well, I wrote you in January. I got a response yesterday, the day before this hearing.

Secretary CHAO. We have lots of letters to answer, but I apologize for that. We will certainly do better in terms of our reply.

Senator BYRD. You've got lots of room to improve.

COAL MINING INSPECTORS

Secretary CHAO. We'll try.

The second thing also is, I think there might be some exception, some people who would take exception that coal miners, operators would be compared to criminals. I think that there are lots and lots of rules and regulations——

Senator BYRD. Nobody is comparing coal miner operators to criminals.

Secretary CHAO. There are lots of rules and laws——

Senator BYRD. Have you ever lived in a coal mining camp?

Secretary CHAO. No. I lived in Queens, New York, in a little tenement house when I came to America.

Senator BYRD. You haven't lived around a coal mine.

Secretary CHAO. No, not really.

Senator BYRD. No. Well, you should try it sometime.

Secretary CHAO. Yes. There are lots of experiences that we should all share, I think, to help us understand the world.

Senator BYRD. You might share that one so we could really talk about coal mine inspections.

Secretary CHAO. Yes, sir.

Senator BYRD. Now, go ahead, will you, if I've interrupted you.

Secretary CHAO. There are lots of rules and regulations, so—I'll make it very short. So we want to help employers and workers understand what their obligations and rights are so that workers can be better protected. That's the whole point about the inspections and the compliance assistance. There has not been any faltering of enforcement, as the numbers that I just cited indicate.

Senator BYRD. I see the light is red. If I may just ask this one final question, Mr. Chairman.

Senator SPECTER. Of course, Senator Byrd.

NATIONAL EMERGENCY GRANTS

Senator BYRD. Thank you.

I have been contacted by the Governor's Office of West Virginia about the slow response from the Labor Department in processing our State's national emergency grant applications. To expedite the release of these emergency job training funds, the Congress annually appropriates money to the Labor Department for the future fiscal year so that the Labor Secretary can quickly allocate these funds as grants, and yet West Virginia has had to wait for 5 months for its application to be processed.

In the meantime, the number of West Virginians waiting for those job training funds has jumped from 500 workers to over 1,200 workers. Why are these emergency funds being delayed?

Secretary CHAO. Well, I hope that's not the norm, and I will look into it, because we have just—I signed off about $107 million of these national emergency grants. We tried to be very prompt in turning them around, and in fact we prefer, we like them better.

Senator BYRD. Would you look into this?

Secretary CHAO. I sure will.

Senator BYRD. And give me a specific response to that question?

Secretary CHAO. Yes, I will.

Senator BYRD. Let me repeat it, why are these emergency funds being delayed?

Secretary CHAO. I hope they're not being delayed, but I will look at them.

Senator BYRD. I beg your pardon?

Secretary CHAO. I hope they're not being delayed.

Senator BYRD. You hope they're not.

Secretary CHAO. No. Sometimes it requires working with the State to make sure that the application comes in the right form, even though it's a very simple application form, and to make sure that the workers are indeed eligible and all that.

Senator BYRD. All right.

Secretary CHAO. But we will certainly take a look.

Senator BYRD. Could you please, not only take a look, but let this subcommittee know your response to that question?

Secretary CHAO. I will.

Senator BYRD. And give me a letter——

Secretary CHAO. I will.

Senator BYRD [continuing]. Addressed to me, with an explanation, and you might elaborate on some of the other answers that you've given me.

Secretary CHAO. I will.

Senator BYRD. I don't find them to be altogether satisfactory, with all due respect to you. Thank you very much.

[The information follows:]

STATUS OF NATIONAL EMERGENCY GRANT REQUEST FOR WEST VIRGINIA

Helping American workers who have lost their jobs is a top priority for this Administration.

The State of West Virginia submitted an application for National Emergency Grant (NEG) funds in the amount of $4,985,714 to serve approximately 450 of the 750 workers impacted by layoffs and closures of coal mines. Companies identified in the NEG application include Pine Ridge Big Mountain No. 16 in Boone County, Ruffner Mine (ARCH) in Logan County, A.T. Massey, Inc. in Boone, McDowell and Raleigh Counties, Colony Bay Surface Mine in Boone County, Bar K Incorporated in Kanawha County, Kanawha Eagle in Boone County and BJM in Nicolas County.

Officials in Department of Labor's Employment and Training Administration are reviewing the request for the NEG funds very closely. Part of this review includes an assessment of existing funds in the state.

—As of the December 2002 reporting period, West Virginia has over $30 million in unexpended WIA Dislocated Worker Program formula funds.

—The United Mine Workers of America was designated by the Congress to receive a PY 2002 hard-mark, which was awarded on October 3, 2002 in the amount of $2 million to serve dislocated mine workers in West Virginia, Pennsylvania, and Virginia.

ETA officials learned that A.T. Massey began to increase coal production, and therefore rescinded the Worker Adjustment and Retraining Notification (WARN) Act notice which announced the lay off of 37 workers. ETA officials also learned that the Ruffner Mine will not be laying off the 260 workers identified in the NEG application. Many of the remaining workers who were impacted by the coal mine closures are accessing services through WIA Dislocated Worker Program formula funds.

You have my assurances that we will monitor the situation closely. When a final decision is made, you will be notified promptly.

Senator SPECTER. Senator Harkin.

NATIONAL EMERGENCY GRANTS

Senator HARKIN. Mr. Chairman, thank you.

I have a followup to Senator Byrd's just recent question about dislocated workers and about the length of time that it's taking to get applications approved. Senator Byrd, I want to give you some examples of what's happened out in our State, and Madam Secretary, I'm going to ask you about this. You say you hope this is not a pattern, but after listening to Senator Byrd and looking at what's happening in my State, I'm wondering if it is a pattern. For example, let me give you some examples: 117 days to approve the application of R. R. Donnelley in Des Moines for 375 workers; 125

days to approve the application for Rockwell-Collins, 153 workers; 111 days to approve the application for International Paper in Clinton for 126 workers; 248 days to approve Iowa dislocated farmer grants for 300 individuals.

That's the delay. Then when the grants were approved, listen what happens.

In June of 2002, the Department of Labor approved a national emergency grant of nearly $300,000 for dislocated workers from Sioux Tools and Terex-Schaeff up in Northwest Iowa. The approval took 83 days, but that was in June of 2002. Only $79,507 has actually been received. A request for the additional $217,865 was submitted last September, and to date there has been no response from DOL.

Secretary CHAO. May I answer that, or——

Senator HARKIN. Sure. Well, I've got some more. You answer that and I'll give you some more.

Secretary CHAO. I will, of course, go back and take a look. Sometimes the national emergency grants are, I don't want to use the word confused, because I don't mean to be insulting, but sometimes they're mixed up with the TAA grants. Now, the TAA grants do take quite a while. On average they take about 4 months.

The national emergency grant is a fairly easy process, so we do tout its flexibility and its ability to move quickly. The TAA grants, on the other hand, are——

Senator HARKIN. I'm told by my staff these are all national emergency grants.

Secretary CHAO. And sometimes the glitch is not with the Department of Labor. Sometimes it goes back to the State Departments of Labor. They have to provide the right information, and the State workforce agencies also share in these issues, because sometimes they don't provide sufficient information that States need to have to use these dollars, so it is a very decentralized system, but generally speaking we are able to move it fairly quickly.

Senator HARKIN. Well, Madam Secretary, would your staff, who is with you, respond why it took so long for R. R. Donnelley?

Secretary CHAO. Sure.

Senator HARKIN. Why it took so long for Rockwell-Collins?

Secretary CHAO. I sure will.

Senator HARKIN. Why it took so long for International Paper in Clinton, and why farmers are always the last?

Secretary CHAO. I hope that's not the case.

Senator HARKIN. Why are farmers always—248 days to approve it for dislocated farmers.

Secretary CHAO. Well, we will see, again, what happened to those, and I want to make sure also that it's not the Department's——

Senator HARKIN. That's why I want to know.

Secretary CHAO. Yes.

Senator HARKIN. I want to know where the glitch is. If you say the glitch maybe some place else, I want to find out about it.

Secretary CHAO. These grants are reviewed and handled by career professionals.

Senator HARKIN. But what's your average time for national emergency grants?

Secretary CHAO. We like to say pretty—you know, I'm a little reluctant now to say how much we like to see, but we have told people that it can come out within a month or so.

Senator HARKIN. Well, I just gave you some examples here that are a lot longer.

How about, can you answer this for me? How about the one that went to Sioux Tools and Terex-Schaeff? In June of 2002 they approved it. That's last June. $79,000 has been received. They submitted the additional request for $217,000 in September, and no response yet.

Secretary CHAO. Again, I don't know the specifics of that.

Senator HARKIN. I'm sure you don't.

Secretary CHAO. I don't know whether it's at the Department or whether it's at the State level, but we'll certainly take a look, but it does require cooperation with the State departments of labor, the State workforce agencies, the WIB boards to make all this happen.

Senator HARKIN. One last one. The last one I mentioned was Sioux Tools.

Secretary CHAO. Right. We'll take a look at all of them.

Senator HARKIN. The last one I've got is $739,073 in January of last year, in 2002, not this January, for workers who lost their jobs when three plants closed, Exide Technologies, that's a battery company, Wabash National and Keokuk-Ferro-Sil. They submitted a request for the final installment for $237,190 last November and they're still waiting.

Secretary CHAO. Sometimes the State work agencies will also submit requests, but these requests may not be truly the——

Senator HARKIN. Well, my time is up.

Secretary CHAO. Okay.

Senator HARKIN. I just want—as long as your staff is here, there are three more Iowa grants pending at the Department.

Secretary CHAO. There is a tendency to ask for the request, but we do take a look at the request, see what the dislocated worker situation is within the particular State or the region, and see from that how best to put out the grant.

Senator HARKIN. Let me just tell you, there is one grant that came in on October 18 of 2002. That's been 164 days now, 164 days, one, two, three, four, five different companies, APAC, Andrew Corporation, Celestica, Charleston Place, and Bluebird Bus, the bus builders, and I'd like to have you take a look at that.

Secretary CHAO. I will do so. There's not very much discretion at my level. I mean, basically this is all done with the career ranks. They have a lot of experience in how these programs are administered, what is required for *x* number of individuals, and this is the analysis that they go through, but we will take a look and, as I mentioned, a lot of workforce investment boards will ask for lots of things sometimes.

Sometimes a grant may be smaller than a request because we will go into a region and see what the actual number of dislocated numbers are, and it could be smaller than the actual requested amount.

Senator HARKIN. Well, I just think the length of time is just unacceptable, how long it's taking.

Secretary CHAO. We'll take a look at it.

Senator HARKIN. I don't know whether it's the bureaucracy or whatever it is, but you're in charge of the bureaucracy. They work for you.

Secretary CHAO. We'll take a look at it.

Senator BYRD. Perhaps a quote from William Wordsworth might be appropriate.

Senator SPECTER. This will come out of your fourth round of questions, Senator.

Senator BYRD. Okay. I expect to be charged for it. Wordsworth said, it matters not how high you may be in your department. You're still responsible for what your lowliest clerk is doing.

Senator SPECTER. Was he a Senator, Senator Byrd?

Senator Byrd is replete with pithy, relevant, instructive quotations. We thank you for that.

Secretary CHAO. I by no means shirk the responsibility, and I just checked, these numbers, unfortunately are not that different from previous years.

Senator HARKIN. They're not——

Secretary CHAO. They're not that different from previous years, but we want to improve, so let's take a look.

Senator HARKIN. But you told me that national emergency grants go out in a matter of just days or weeks, and I've given you some that take months.

Secretary CHAO. Well, we've been trying to improve them, but those numbers that you cite are not different than previous years.

Senator HARKIN. So you're not doing any better now than you've ever done.

Secretary CHAO. We're trying, but obviously by your example——

Senator HARKIN. I hate to be so provocative—I hate to be provocative, but when you tell me that emergency grants go out in a matter of days or weeks, and I've given you some that have taken months, you come back and tell me, well, it's the same as it's always been, so don't——

Secretary CHAO. Well, I'm just trying to say——

Senator HARKIN. Something's not adding up.

Secretary CHAO. We're doing our best, but that's been the record. We're going to continuously improve, and we'll check into the ones that you want.

Senator HARKIN. Thank you.

[The information follows:]

STATUS OF NATIONAL EMERGENCY GRANT REQUESTS FOR IOWA

The President and I are committed to helping displaced workers access the job and skills training they need to find new jobs that will enable them to provide for themselves and their families.

In Program Year 2002, which began on July 1, 2002, the Department awarded $2,550,470 in National Emergency Grant funds to provide reemployment assistance to workers dislocated as a result of the closure of an International Paper plant, workers laid off from Rockwell Collins avionics plant, Ball Corps, Mau Trucking, MCI Worldcom, Inc. and farmers.

Most recently, I approved a request for $217,000 to aid 55 Iowa workers dislocated from Sioux Tools and Terex-Schaeff located in Sioux City, Iowa. The project will be operated by the Western Iowa Tech Community College, and will provide reemployment services, including job search assistance, job development, job placement, basic skills training and counseling.

Officials in the Employment and Training Administration are also reviewing three other National Emergency Grant applications from Iowa, including a request for in-

cremental funding for a Northern Engraving project, APAC Teleservices and American Growers Insurance Company. Part of this review includes an assessment of existing funds in the state. As of December 2002, which is the most recent WIA reporting period, Iowa has an unexpended balance of $4,630,710. These funds can also be used to provide assistance to workers impacted by plant closures and layoffs.

You have my assurances that we will monitor the situation closely. When a final decision is made, you will be notified promptly.

ERGONOMICS INSPECTIONS

Senator SPECTER. Secretary Chao, I don't want to spend any more time on ergonomics because I've asked you to supply the materials in writing, but when you come up with this figure of 37,000 inspections, I didn't want to pursue it, but staff has advised me that that's the total number of inspections conducted by OSHA, and I had quoted for you 388 inspections of nursing homes and 103 on others. What's the relevance in responding about 37,000 inspections when the question related to ergonomics inspections?

Secretary CHAO. Just to—well, maybe it didn't—I thought it made sense at the time, but I'm trying to show the number of inspections overall that OSHA does. In fact, that's been an increase of more than 7 percent, so we have stepped up our inspections.

Senator SPECTER. But the question is not about the total number of inspections. The question is about ergonomics inspections, in an attempt to——

Secretary CHAO. Well——

Senator SPECTER. May I finish?

Secretary CHAO. Yes, please.

LM–2 PROPOSED REGULATION

Senator SPECTER. In an attempt to evaluate whether your voluntary system is working. It's very hard to—well, you get the point, Secretary Chao.

Let me come to the question of the new report requirements, and I had written to you raising some questions as to how these reporting requirements contrasted with other reporting requirements of the Small Business Administration or for corporations under the Sarbanes act or by the General Accounting Office, and I got your response, and I noted your statement that I should meet directly with the Department's Inspector General and Chief of the Division of Enforcement for the Department's Office of Labor Management Standards, and candidly that's quite an undertaking for me to do, but I do want to pursue this question, starting at the staff level.

We may need a hearing on this generally, but in the few minutes we have remaining on this hearing, Madam Secretary, let me ask you to compare reporting requirements for small businesses which go to annual receipts under $6 million, contrasted with the requirement for labor unions with annual receipts under $200,000. Why should there be such a significant divergence on reporting requirements?

Secretary CHAO. The $200,000 limit is what is currently in the rules, stemming from the statute. We have not changed that, number one. That's the current level.

Number two, when comparing the whole issue about accountability and transparency with the labor unions, when you compare them with any other organization, any other sector, there are basi-

cally four layers of protection. There is usually a requirement for quantitative information, for qualitative information pertaining to materiality, for example, there is also another layer of internal controls mandated by the law, and also internal audits.

Senator SPECTER. When you raise the issue of materiality, you move into what the Securities and Exchange Commission does, and their standards require the disclosure of, as you put it, material information.

Madam Secretary——

Secretary CHAO. The disclosure just refers to the first——

Senator SPECTER. Madam Secretary—I'm asking you a question right now——

Secretary CHAO. Please.

Senator SPECTER. Madam Secretary.

Should labor unions be required to have more detailed reporting requirements than their corporate, private corporate counterparts?

Secretary CHAO. Well, currently they do not, and under the proposed new rule they still will not.

Senator SPECTER. Well, that's what I would like to work out. I commend—there's no doubt about the need for reporting, and for knowing what goes on with union records, and I've had some experience on that going back to the days of the McClellan Committee, which investigated labor racketeering back when John F. Kennedy was a Senator, and when I was an assistant district attorney I got the first conviction on labor racketeers arising from the investigations of the McClellan Committee.

Six union leaders went to jail after their conviction for conspiracy to cheat and defraud Local 107 of the Teamsters Union, and I have some appreciation for this sort of an inquiry, but what I would like to do initially at the staff level, Madam Secretary, and we will be propounding some questions for the record, is to take a look at what has been done and what are the requirements for small businesses, what are the requirements for corporate America.

I appreciate your interest in wanting to find out what is going on, and this subcommittee shares your concern, and we will work with you on that, but we want to see to it that there's an appropriate balance, and the comparison is always made on so many lines, financing of elections reporting, to have an equitable burden as you take a look at corporate America with unionized workers.

Secretary CHAO. There's a great disparity, and the unions do not have a fraction of the reporting requirements as required by corporations.

Senator SPECTER. Senator Harkin, do you have another line of questions?

LM–2 REPORTING REQUIREMENTS

Senator HARKIN. I'd like to follow up on that, Madam Secretary. Words—I'm listening to the words you're using. You say that maybe the unions don't have the reporting requirements of corporations. You mean publicly held corporations.

Let me ask you this question. A labor union with receipts of $500,000 a year, its reporting requirements compared to a privately held company—not a public corporation. Now, public corporations, you're right, they do have to have more reporting than

labor unions. That's because they're publicly held. I'm talking about a private corporation. A labor union is not a publicly held corporation, so compare for me a union with receipts of $500,000 with a privately held business that makes $500,000, and compare for me the reporting requirements, would you, please?

Secretary CHAO. I'd be more than glad to. First of all——

Senator HARKIN. And you say——

Secretary CHAO. I would be glad to.

Senator HARKIN. Okay.

Secretary CHAO. The comparison is not analogous. First of all, most people are partnerships, single proprietorships, or small companies who have some degree of control over their resources. If you are a union member, you do not have control over your resources. Ten of the top 20 labor unions do not have any audits by the Office of Labor Management Standards. There are only two forms that they currently have to file.

Senator HARKIN. 10 of the top 20——

Secretary CHAO. That's true.

Senator HARKIN. 20 top in what regard?

Secretary CHAO. Largest.

Senator HARKIN. 10 of the top 20 largest unions have no what?

Secretary CHAO. Have never had an audit by OLMS.

Senator HARKIN. Have never had an audit by whom?

Secretary CHAO. The Office of Labor Management Standards, which is the office within the Department of Labor, the only office in the Government, aside from the IRS——

Senator HARKIN. Is that because the OLMS is prohibited by law from auditing them?

Secretary CHAO. No. They don't have the resources. That was under the Landrum-Griffith act. They don't have the resources. Also, there's no requirement for audited financial statements. There are no requirements for auditing for compiling financial statements according to the GAAP, that's generally accepted accounting practices, or generally accepted accounting standards. There are no whistleblower protections. There are no internal controls mandated by the law. All of this is mandated in most cases for corporations and for small companies. You have to have audited statements. You have to have certified public statements.

Senator HARKIN. By corporations.

Secretary CHAO. Even private companies, you have to have——

Senator HARKIN. What do private companies have to have?

Secretary CHAO. The larger issue is, in a small company——

Senator HARKIN. I think you misspoke, but go ahead.

Secretary CHAO. In a small company, most stakeholders have some control over the resources of that entity.

Senator HARKIN. Well, I would say that in a union they have some because the union officers are elected. There's a vote, a democratic vote.

Secretary CHAO. There are other issues about disclosure, quantitative disclosure, qualitative disclosure, internal controls, and internal audits. None of those occur.

Senator HARKIN. Has any of those top 10 of the top 20 unions that you say they've never been audited by OLMS, are you aware if they've ever been audited with outside auditors?

Secretary CHAO. They probably have, but it's not mandated by law, as it is with other organizations.

Senator HARKIN. But if they've been audited by outside auditors, and those audits are available to its membership and to others——

UNION AUDITS

Secretary CHAO. Whether it is or not, we don't quite know. There have been complaints that they've not been available. Certainly the union leadership claim that they are available, and then we also have heard from some certain members that it's not available.

Senator HARKIN. The recent thing about this union, ULICO thing, you know, that's sort of been in the news lately, I'm told that that came to light not because of you or because of the Department of Labor or anything else, it came because of audits that were done by the unions themselves. It was a voluntary program and they brought it to light. Is that not true?

Secretary CHAO. That is not true. We had heard about it before, and it was under investigation. The same thing with the American Teachers Federation.

Senator HARKIN. But who did the audits?

Secretary CHAO. That I'm not sure of.

Senator HARKIN. I was told that was internal audits, or audits, not internal, but audits that were done by outside CPAs and stuff that came in that the unions asked to have it audited, and that's how they found it.

Secretary CHAO. We have 11 criminal convictions a month, and not all of that is self-revealed through the unions.

Senator HARKIN. You've got 11 criminal convictions a month on what, criminal convictions of whom, of what?

Secretary CHAO. Of labor unions. We have about 200 audits a year. It's a very enfeebled office at this point. Its budget and FTEs were cut more than 40 percent in the last 10 years, so this small office conducts about 200 audits a year, and there are investigations ongoing on others. On average there are about 11 criminal convictions a month.

Senator HARKIN. A month.

Secretary CHAO. Yes.

Senator HARKIN. Convictions, by you or by whom? Convictions by whom?

Secretary CHAO. The courts, Justice Department.

Senator HARKIN. Are these under State courts? Are these Federal cases you bring? I mean, 11 criminal convictions a month, are these because of your investigations? Is that what you're saying?

Secretary CHAO. A lot of them are instigated not by us but by the Office of the Inspector General, because they are in charge of a lot, and then also by the Office of Labor Management Standards, yes.

Senator HARKIN. All right. When you submit the comparisons, don't just use publicly held corporations. I want you to use privately held companies, closely held companies that would have the same kind of receipts in a year as the labor union, and compare them to see what the reporting requirements are.

Secretary CHAO. Labor unions basically don't report very much today, anyway. They only report two forms to the Office of Labor Management Standards.

Senator HARKIN. Well, what does a privately held company with the same receipts have to report?

Secretary CHAO. That's not an analogous comparison.

Senator HARKIN. To try to compare it to publicly held corporations, why is that analogous?

Secretary CHAO. No, the labor unions actually wanted to be compared to publicly accounted public companies. They claim that they are held to a higher standard than public corporations, which is not true.

Senator HARKIN. Well, this could go on and on. Thank you very much, Madam Secretary.

[The information follows:]

COMPARISON OF THE FINANCIAL DISCLOSURE REGIMES FOR LABOR UNIONS AND PRIVATELY HELD COMPANIES

Legally mandated financial disclosure regimes for both unions and publicly held corporations are designed primarily to address a fundamental problem common to both institutions—the principal/agent dilemma. This dilemma exists whenever managerial control of an entity lies beyond the direct control of the people who fund the entity. This occurs in both unions and publicly held companies. Corporate and union financial disclosure regimes are supposed to reduce the informational advantages agents have over principals and permit principals to monitor and assess the performance of agents. Adequate transparency encourages union officers and corporate directors (agents) who are elected by union members and corporate shareholder (principals) to conduct the business of their organizations in the best interests of the people who provide the operating funds. Agents failing to do so can be removed through the mechanisms of corporate and union democracy.

There is no principal/agent dilemma in a privately held enterprise where the operator of the business is also the source of the venture's financing. There is no principal to perform the monitoring and no agent to be monitored. While privately held companies are required to make certain financial disclosures related to franchise taxes, Small Business Administration loans, FCC licenses and other regulatory schemes, these disclosures are designed to assess taxes, fees or eligibility for government provided benefits, not to ensure transparency of managerial performance. The only scenario in which it is rational to compare the financial disclosure regime of a privately held company to a union is when a privately held firm creates a principal/agent relationship by accepting funding through the venture capital markets.

The Labor Management Reporting and Disclosure Act of 1959 (LMRDA) established a unique financial disclosure regime for labor organizations designed for two purposes. First it was supposed to provide union members insight into how union officials managed members' dues so that they could make informed decisions during union elections. Second, it was supposed to deter the pervasive infiltration of organized crime into unions that was highlighted during the McClellan hearings.

The disclosure regime for labor organizations has not been materially updated in more than four decades. The modernized union disclosure regime on which the Department of Labor requested public comment is far less rigorous than the disclosure regime currently mandated for publicly held companies following the passage of Sarbanes-Oxley and in many respects less rigorous than the legally enforceable transparency regimes that privately held firms accept as a condition of receiving venture capital funding. The efficacy of these disclosure systems as a means to address the principal/agent dilemma and the burden associated with them can be evaluated by the extent to which they provide adequate quantitative information; qualitative information; and audit requirements and internal management controls designed to guarantee the integrity of qualitative and quantitative disclosures.

Senator SPECTER. Thank you, Senator Harkin. Thank you very much, Madam Secretary, for coming in today. It is a big job to administer the Department of Labor, and we are very pleased to work with you on the budget. It's an enormous responsibility to have the $11.5 billion allocation of funding and all of the responsibilities

which you have, and budgets are always difficult, and in allocating these budget resources, as you know, this subcommittee has to balance off Labor requests with Education requests and with Health and Human Service requests because it is a unified budget the subcommittee has, and we have to make the allocations. When you talk about worker safety and worker training and contrast it with Head Start and Pell Grants and the National Institutes of Health, it is difficult.

Thank you for coming in today.

Secretary CHAO. Thank you. We're very committed, obviously, to helping workers train, and we want to work with the committee.

Senator SPECTER. Thank you.

Secretary CHAO. Thank you.

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Senator SPECTER. We have received the prepared statement of Senator Thad Cochran that will be made part of the hearing record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, I am pleased to join you in welcoming Secretary Chao. I look forward to working with her on issues that are of special importance to Mississippi and to our nation.

The migrant and seasonal farm worker housing program is of particular interest to me.

In the past, this subcommittee has included report language directing the continuation of this small, but important program that assists farm workers gain better housing. Since 1983, I have worked with the Department to ensure a network of local organizations, including one in my state, receives funding to plan, develop, and manage housing for migrant and seasonal farm workers. There is now a well established network of local housing organizations that receives these funds.

I look forward to working with you, Madam Secretary, on this and other important Department of Labor programs. Thank you.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

HISPANIC AND IMMIGRANT WORKERS

Question. Over the past years, there has been an alarming increase in fatalities among Hispanic and Immigrant Workers. The Department of Labor has acknowledged this fact and has included $2.2 million in the fiscal year 2004 budget request for a Hispanic Worker Initiative. At the same time that this program is being proposed, however, the Administration is proposing to cut funds for worker training and education grants by more than $7 million. Many of the programs conducted under these training grants have been directed towards Hispanic and Immigrant workers, the very workers that DOL has stated are a priority. Why is the Administration proposing to cut funds directed towards training and education, including programs targeted at Hispanic and Immigrant workers? Have these programs been unsuccessful?

Answer. OSHA has included an increase of $5,250,000 in its fiscal year 2004 budget to expand outreach and assistance activities, almost half of which will be dedicated to efforts to reach non-English speaking, hard-to-reach and contingent

workers. This is in addition to a large number of ongoing programs designed to reach, train and educate these workers.

The President is also requesting $4,000,000 for OSHA training and education grants in fiscal year 2004. We continue to believe that the emphasis for OSHA's training and education grants should be the development and distribution of training materials for the broadest possible audience. To meet the changing needs of employers, and to take advantage of new technologies, OSHA has outlined a revised grant program that would fund short-term grants to nonprofit organizations to develop, evaluate and validate safety and health training materials for OSHA that would primarily be distributed to the public via the Web. The training materials would be targeted principally to employees and small business employers and could be tailored to the varying needs of selected industries and workers. This change would make more materials available for employers and other interested parties to utilize for training their workers. These materials would also be a useful resource for OSHA compliance assistance specialists by complementing the services they provide. Rather than teaching a few workers at a time, we will be able to develop a variety of new training materials on a continuing basis to benefit more workers throughout the country.

Question. What specifically does the Department propose to do under the new Hispanic Worker Initiative that is proposed? How will these initiatives differ from the programs that have been conducted under the training grant program?

Answer. The Department is expanding its efforts to address the safety and health of employees in hard-to-reach sectors of the workforce, including young workers, as well as Hispanic and other non-English-speaking workers. For example, OSHA plans to improve the operations of its toll-free number, which offers assistance in English and Spanish. OSHA will also expand its current web page for Spanish speakers and plans to create a Spanish version of many of the agency's information publications. A Spanish version of "All About OSHA," the pamphlet that describes the agency's responsibilities and workers' rights, already exists. OSHA is also forming partnerships with groups like the Hispanic Contractors of America, INS., to raise awareness of safety and health assistance offered by OSHA and its state partners.

The Department is also actively recruiting Spanish-speaking employees to work in front line positions. For example, OSHA currently has 180 Spanish-speaking employees in Federal and State OSHA programs.

CONSOLIDATION OF EMPLOYMENT AND TRAINING PROGRAMS

Question. The administration proposes consolidating adult, and dislocated worker funding under the WIA and Employment Service programs into a single block grant. An historic function of federal job training funding is to target dollars to areas and individuals of greatest need.

The adult WIA program allocates funding according to poverty levels to help communities with large numbers of economically disadvantaged workers. Dislocated worker funding is targeted to communities with high unemployment, and it also provides for state Rapid Response programs to intervene early with help for workers and companies in trouble.

The result of the administration's proposed block grant is to eliminate discrete programs that provide vital services to groups with special needs and could pit welfare recipients against unemployed workers in competition for limited funds.

Why does the administration seek to block grant programs at a time when there is a continued need for targeted, fully-funded programs aimed at the special needs of disadvantaged and dislocated workers?

Answer. The Administration's proposal is to consolidate the three separate funding streams that currently provide overlapping employment-related services to adults into a single, more flexible, comprehensive and effective program. The three separate streams, while providing similar services, currently have separate funding formulas, eligibility criteria, performance measures, reporting requirements, and other elements that reduce efficiency, promote duplication of efforts, and do not enhance the provision of services. Consistent with the principles of program integration underlying the Workforce Investment Act of 1998 (WIA), this consolidation of funding streams would simplify and enhance the delivery of services to adults.

The critical services authorized under the current separate programs to meet the needs of special populations would continue to be authorized under the consolidated comprehensive program, but without the burdensome administrative requirements that currently result from having to track three separate streams of funding.

Funds under the new program will be allocated to states by formula, and a portion will be held in reserve at the national level in a discretionary account for Na-

tional Dislocated Worker Grants (currently "National Emergency Grants"), demonstration grants and technical assistance.

At the state level, funds will be allocated to local areas. Governors would maintain a reserve for statewide activities, including rapid response, support for core services in the One Stop program, and demonstration projects.

At the local level, the core, intensive and training services currently available under the separate programs would be available through One-Stop career centers under the new comprehensive program, with enhanced flexibility to determine the appropriate combination of services. Priorities with respect to providing intensive and training services would be given to the unemployed and, if local funding available to serve low-income individuals is insufficient, to low-income workers. The core services would be available on a universal basis to job seekers and employers.

The Administration believes this proposal enhances, rather than diminishes, the ability of States and local areas to tailor services to meet the special needs of disadvantaged, dislocated and other workers.

Question. States have not used the flexibility they have right now to receive waivers and to transfer funds between adult and dislocated worker programs. So why does the administration feel the need to consolidate adult and dislocated worker programs when states haven't taken advantage of the flexibility they currently have?

Answer. States have taken advantage of the waiver authority in the current law, with 36 states requesting waivers, and many of them requesting multiple waivers of a variety of provisions in the law. In addition, over half of the states have transferred funds between their adult and dislocated worker programs. It should also be noted that because the current waiver authority contains significant restrictions on the requirements that may be waived, the Department has been unable to approve a number of waiver requests that we have received. This experience indicates a significant interest on the part of the states for greater flexibility in the statute.

The Administration believes the consolidation of the three funding streams (Adult, Dislocated Workers, and Wagner-Peyser) into a single, comprehensive program for adults would provide significant flexibility that will result in enhancing the provision of services to job seekers and employers.

ELIMINATION OF THE UNITED STATES EMPLOYMENT SERVICE

Question. The administration proposes to eliminate the 60-year-old United States Employment Service (ES), a federal-state partnership that provides assistance in matching job seekers with employers. This proposal will replace the "honest broker" function of the ES with myriad organizations whose purpose will be driven by profit, not public service.

The U.S. Employment Service provides a nationwide public labor exchange for all workers and employers. How does the Department expect fifty states to carry out this national purpose without compromising or undermining the principle of universal access and a free, public national labor exchange?

Answer. The universal labor exchange services currently provided under the Wagner-Peyser Act are also required to be provided under the current WIA adult formula program, and labor exchange services for dislocated workers are required to be provided under the WIA dislocated worker formula program. All three programs are to make these services available through the One-Stop delivery system established in each local area under WIA.

Rather than have these overlapping and duplicative requirements for the provision of labor exchange services under three different programs, the Administration believes the three funding streams should be consolidated into a single, comprehensive program for adults which includes as a key element the availability of universal public labor exchange services for all job seekers and employers. Rather than undermining or compromising the principle of universally accessible labor exchange services, the Administration believes the consolidation would strengthen and enhance the provision of those services.

Question. The U.S. Employment Service provides a range of services in addition to labor exchange including special assistance to migrant and seasonal farmworkers and veterans. It also conducts important labor market research and labor certification functions. How will the Department ensure that these functions are continued?

Answer. The functions described in the question will continue to be carried out.

The assistance to migrant and seasonal farmworkers will be carried out through the One-Stop delivery system under the consolidated WIA adult program. Similarly, the special programs for veterans, the Disabled Veterans Outreach Program (DVOP) and Local Veterans Employment Representatives (LVER) program, that assist vet-

erans in job placement will be carried out in coordination with the consolidated adult program through the One-Stop delivery system.

Other initiatives funded through the America's Labor Market Information System (ALMIS)/One-Stop line item would also continue. These initiatives create the foundation for a Workforce Information System that provides for the data collection, aggregation, formatting, and delivery needed for day-to-day decision-making by our One-Stop partners and for the efficient delivery of information and labor exchange services through a set of Internet-based electronic tools. The funds are also used to insure that our information delivery is up to the high-quality standards set for e-Government.

The ALMIS/One-Stop budget for fiscal year 2004 has been re-aligned with ETA's priorities and strategic plan. The budget requested will provide sufficient funding for a comprehensive Workforce Information System and for the continued development and delivery of information through the Career One-Stop set of national electronic tools.

The Department of Labor will continue to provide funds to State Workforce Agencies to continue to perform certain alien labor certification functions.

TRADE ADJUSTMENT ASSISTANCE (TAA) PROGRAM

Question. The new TAA program significantly increased the number of workers who are eligible for training, income support, and health care. Estimates are that the TAA program enrollments will double. Congress authorized $10 million for TAA health care programs in fiscal year 2004 yet the administration proposes no new funding to provide states with the resources necessary to administer the new health care tax credit and provide interim coverage for TAA-eligible individuals.

Given the expected demand for services, how can the Department of Labor expect the already strapped National Emergency Grant (NEG) program under WIA to provide states with resources to administer a complicated health care tax credit program and to provide interim health coverage to the thousands of TAA-eligible participants?

Answer. As you know, the Trade Adjustment Assistance Reform Act of 2002 established new mechanisms by which certain TAA participants, as well as eligible Pension Benefit Guaranty Corporation pension recipients, can receive assistance in covering the cost of health insurance.

These mechanisms include two different types of National Emergency Grants (NEGs). The first NEG is authorized under the new section 173(f) of WIA and is primarily to provide administrative support to the States in carrying out the health tax credit (HCTC). The second NEG is authorized under the new section 173(g) of WIA and is primarily to provide interim assistance in paying for qualified coverage until the HCTC is available on an advanceable basis. Since the law requires that the advanceable credit be available not later than August 1, 2003, we do not believe additional resources will be needed in fiscal year 2004 and thereafter for the interim assistance NEG. Fifty million was appropriated to carry out that NEG in fiscal year 2002 and remains available.

For administrative support NEGs the Congress appropriated $10 million in fiscal year 2002 and $30 million in fiscal year 2003. Since the program is new, it is difficult to determine the appropriate level of resources that will be needed in future fiscal years. Beginning in fiscal year 2004 the Administration believes that in lieu of a separate appropriation this NEG would be better administered if funded under the same source of funding as the other NEGs for dislocated workers. This would provide the Secretary with appropriate flexibility in managing NEG funds so that the Secretary could shift more funds to these HCTC activities if needed, or if additional resources are not needed, to use the funds for other dislocated worker assistance.

H–1B TRAINING PROGRAMS

Question. The Administration will not seek to renew the H–1B training program, which created a $98 million training fund for U.S. workers, paid for through employers' H–1B visa application fees. At the same time, the budget requests an increase of $49.5 million to expedite processing of permanent foreign labor certifications.

How can the administration abandon worker training in skill shortage occupations when H–1B visas will still be provided to thousands of foreign workers?

Answer. The Administration is not abandoning job training in skill shortage occupations. That is one of the important functions of all of the job training programs administered by the Department, including the formula programs administered by States and local areas under title I of WIA. The Department is continuing to work

to ensure job training is linked to occupations in demand, particularly skill shortage occupations.

It may also be noted that Department has awarded over $218 million through 90 H–1B technical skills training grants. In January 2003, the Department issued a revised Solicitation for Grant Applications, and approximately $200 million in additional funding is available for grants.

We will continue to make funds available for H–1B Technical Skills Training Grants, as authorized under the law, until the funds are expended.

Grants for the H–1B technical skills grants program have been awarded under the authority of Section 171 of the Workforce Investment Act (WIA), which requires programs and activities carried out under that section be thoroughly evaluated. An evaluation being conducted by Lee Bruno and Associates and Westat Research is examining all aspects of the program, including how grantees have innovated to develop effective tools and approaches; the extent to which participants have achieved increased skill levels resulting in degrees, licensures, certifications, or occupational/wage upgrades; and the feasibility of examining the programs' net impact on the employment-related outcomes of trainees and the employment of foreign workers with H–1B visas.

It is the Department's intent, based on this and other studies, to examine what strategies do and do not work in technical high skill training. We plan to share the knowledge gained through these studies with States and local Workforce Investment Boards who administer the WIA program, so that knowledge can be applied in the administration of the job training activities that are funded at the State and local level under WIA, and to other programs administered by the Department, such as Trade Adjustment Assistance.

WIA YOUTH PROGRAMS

Question. At a time when increasing numbers of young people are at-risk in the labor market, the administration proposes to cut youth training programs and to phase out the Youth Opportunity Grants program, which provides at-risk youth education and training opportunities in high-poverty areas. It also proposes to limit WIA Youth Activities formula program to out-of-school youth.

Why has the administration cut funding for programs designed to help the most at-risk students, including those in- and out-of-school?

Answer. Reaching out to out-of-school youth is very important and not the focus of other Federal youth programs. School dropouts and other out-of-school youth deficient in basic skills need help in reconnecting with the education system and getting the necessary skills to find employment. Our proposal will target this hardest-to-reach population, which is most in need of services, while the Administration has proposed that the Department of Education focus on in-school youth.

This program will target DOL's formula resources to out-of-school youth programs, providing services that have proven effective in assisting such youth. Our youth investments will focus on providing young people with a strong, core academic foundation in conjunction with post secondary skills certifications or degrees, and transitions to career path employment.

We will apply what we have learned regarding how to better coordinate with local community and faith-based organizations in serving these youth; and how to work with the local private sector to set up internships and other employment experience opportunities for these youth.

We will also apply what we have learned to enhance coordination with the local juvenile justice system to serve youth returning home from correctional facilities and youth being put on probation and how to better coordinate with major employers such as UPS and Federal Express to provide employment opportunities for out-of-school youth.

Question. Why is the administration abandoning help to at-risk, in-school youth?

Answer. The Administration's budget does not abandon help to at-risk, in-school youth. The proposal targets resources to those youth most in need of assistance to reconnect to the education and workforce systems-specifically school dropouts and other out-of-school youth who are basic skills deficient. The Administration has proposed that the Department of Education focus on in-school youth. The new WIA Youth program would be funded at $1.001 billion in fiscal year 2004. Seventy-five percent of the funds will be allocated by formula to states to serve out-of-school youth. It may be noted that the remaining 25 percent will be reserved for national challenge grants, which may be used for a number of activities to assist youth in acquiring the skills, credentials, and employment experience necessary to succeed in the labor market. Those grants could include services to some at-risk in-school youth. However, the primary purpose of the revised youth program is to target re-

source to out-of-school youth who are currently underserved and most in need of the assistance the WIA youth program can provide.

PENSION OPERATIONS

Question. The President's fiscal year 2004 budget includes a provision to eliminate the limit on administrative expenses of the Pension Benefit Guaranty Corporation (PBGC). Shouldn't we be tightening up on the definition of the administrative expense limitation, instead of ceding control to the Executive Branch to determine spending?

Answer. Although the President's budget proposes eliminating the administrative expenses limitation for the Pension Benefit Guaranty Corporation (PBGC), it actually would provide a greater degree of Congressional oversight for PBGC's entire budget than under the current process by:

—Simplifying PBGC's budget structure with a single funding source and making it more transparent to its stakeholders in terms of cost of administration for terminated pension plans and the on-going pension insurance program.

—Providing a more meaningful presentation of all of PBGC's operational expenses.

—Reviewing mid-year operating budget adjustments necessitated by termination of large pension plans not identified in the annual budget request process.

Currently, Congress reviews PBGC's entire operational budget each year as part of its appropriations process following submission of the President's Budget. Over 90 percent of PBGC's work is now devoted to the termination, trusteeship and administration of failed pension plans in the private sector. Funding for this work comes from PBGC's trust funds, which are made up of the private assets transferred to PBGC from terminated pension plans when PBGC assumes responsibility for their administration. These are not appropriated funds.

For several years, PBGC has had two operational budgets: one coming from the trust funds for plan termination-related work and the second coming from PBGC's collected premium revenues paid by on-going, defined benefit pension plans. The premium revenues constitute a permanent appropriation. As PBGC's plan termination work has escalated in recent years, the amount of its operational expenses paid by the trust funds has also risen to over 90 percent.

Continuing to manage two operational budgets for a relatively small agency has proved both burdensome and confusing to stakeholders not dealing with internal budget matters. The President has proposed to simplify PBGC's operational budget by providing a single source of funding coming from the trust funds. In addition, he has proposed that Congress be able to review PBGC reapportionment requests from OMB when a major pension plan termination(s) cause PBGC's operations to expand. These reapportionments have in recent years resulted in substantial increases in PBGC's budget coming from the trust funds in order to quickly support processing of very large terminated pension plans such as TWA and LTV Steel. Over the years, PBGC has used its reapportionment flexibility in only the most serious situations. Although this use has resulted in substantial increases, PBGC expenses per participant have substantially decreased over the last 10 years.

Under the new proposal, PBGC's full annual budget request would be subject to Congressional review—not just during the normal appropriations cycle but throughout the year. Congress would receive advance notice of reapportionment requests, which would afford it an opportunity it does not currently have to raise questions and request additional information before any new funds could be used.

YOUNG OFFENDERS

Question. Your budget justification material states that the United States has experienced rapid growth in the number of people who are incarcerated or under supervision of the criminal justice system. It further states that an estimated 500,000 inmates will return to communities this year. Yet you are proposing termination of the Responsible Reintegration of Young Offenders program, which currently serves 10,400 participants with a budget of $55 million.

Shouldn't we be expanding this pilot program, and not terminating it?

Answer. In 1998, the Department of Labor initiated a five-year Youth Offender Demonstration Project to assist the reentry needs of ex-offenders and at-risk youth. The program is currently in it fifth year.

We are applying what we have learned from the Youth Offender Program to the reauthorization of the WIA youth formula program, which will target resources to out-of-school youth, including youth coming out of the juvenile justice system and will integrate Youth programs with the One-Stop system. We believe this targeted approach to the WIA youth program will enhance the effectiveness of our efforts to

help those served by the Youth Offender Program, as well as school dropouts and other out-of-school youth.

Question. What other resources are available to assist these young people?

Answer. During 2004, the Department will provide technical assistance to transition the Youth Offender Demonstration Project directly to state and local workforce agencies. We will share the demonstration findings and disseminate information to local communities about best practices for serving youth offenders in the existing One-Stop delivery system, using formula WIA, Wagner-Peyser Act and other funds that have been shown through research to strengthen and expand local partnerships and enhance One-Stop services to such youth.

This year, the Department, in partnership with the Departments of Justice and Health and Human Services and other cabinet agencies, supported a companion effort called the Serious and Violent Offender Reentry "Coming Home" Initiative, which provided grants to 68 communities totaling $100 million ($48 million of which is Department of Labor funds) to address the reentry problems of the most serious ex-offenders.

NATIONAL LABOR RELATIONS BOARD

Question. The National Labor Relations Board (NLRB) is an independent federal agency (under Relateds, not under Labor) which was created in Congress in 1935 to administer the National Labor Relations Act. The two primary functions of the NLRB are to: (1) prevent and remedy statutorily defined unfair labor practices; and (2) to conduct secret-ballot elections to determine whether employees wish to be represented by a union. Due to lack of FTEs and being unable to hire new staff because of the fiscal year 2002 levels of last year, the backload of unfair labor practice cases has increased dramatically.

	Fiscal year—		
	2001	2002	2003 (estimate)
Case Backload by the end of	970	1,496	2,346

The NLRB's main function is to help solve disputes regarding unfair labor practices, thus often acting as a liaison between the Unions, and company management. However, the backlog in unfinished cases is growing annually. We recognize that this is a federal agency completely independent from your own, however their role in labor matters is vital. Can you give us an idea of the workload of cases that the NLRB handles and their budgetary needs? What importance do you place on increased funding for this independent agency? Of what importance would you judge this agency in helping mediate and settle labor practices, and to act as this sort of liaison?

Answer. While the Department is aware of the important role played by the NLRB in resolving issues under the National Labor Relations Act, that agency is, as your question recognized, completely independent. The Department is not involved in the preparation of the budget for the NLRB and has no supervisory role with respect to the operations of that agency. Accordingly, the Department is not in a position to comment on the NLRB's workload or budget needs.

ERGONOMICS BUDGET

Question. What level of funding has been targeted to support your "comprehensive approach" to ergonomics in the fiscal year 2003 budget and the fiscal year 2004 budget request? For which activities has funding been requested?

Answer. The resources utilized to address ergonomics in both the fiscal year 2003 and fiscal year 2004 budget request are contained within all of OSHA's budget activities and are not separately identified or earmarked to address ergonomics or any other specific issue. Rather, the comprehensive approach to ergonomics involves focused activity by the entire agency in addressing the four prongs of the ergonomics policy: industry specific and task-specific guidelines, strong enforcement, outreach and assistance, and research.

Question. How many FTE's have been assigned to work on ergonomics?

Answer. The agency has not specifically identified or tracked the number of staff working on ergonomics. The staff necessary to address ergonomic concerns is available as needed within the ongoing enforcement, outreach, and regulatory activities of the agency.

Question. How many ergonomists does OSHA currently employ? What are their responsibilities?

Answer. Although there is no formal Federal job classification titled "ergonomist," OSHA currently employs three Certified Professional Ergonomists. Two of these ergonomists are employed in two different Regional Offices and the third works at our Salt Lake Technical Center. Their responsibilities include providing training and assistance to compliance staff, outreach and assistance to the regulated community, and serving on the Ergonomics Response Team. The agency also employs six compliance officers who have advanced degrees in industrial engineering, with concentrations in ergonomics; nearly 30 regional personnel who have extensive training in ergonomic interventions in specific industries, such as meat-packing and textiles; and three Health Response Team members with extensive ergonomics expertise and training.

ERGONOMICS ENFORCEMENT AND GUIDELINES

Question. How many enforcement actions has OSHA taken pertaining to ergonomic hazards during fiscal year 2002 and fiscal year 2003 to date?

Answer. Inspections under OSHA's National Emphasis Program (NEP) for Nursing and Personal Care Facilities, which focuses on patient-handling hazards, began on September 17, 2002. Over the past winter, Regional and Area Offices implemented Local Emphasis Programs (LEPs) to address ergonomics in several other industries with high rates of musculoskeletal disorders.

In all, OSHA has assessed ergonomic conditions in 675 of the inspections opened between January 1, 2002 and March 31, 2003. Of these inspections, 469 have been in nursing and personal care facilities pursuant to the NEP for this industry and 156 have been in other industries, including 50 inspections in industries targeted by ergonomic-related Local and Regional Emphasis Programs.

Inspection type	Time period	Number of inspections
Nursing Homes under the Nursing Home NEP	September 17, 2002 through March 31, 2003	469
Ergonomic Related—Non-Nursing Homes	January 1, 2002 through March 31, 2003	106
LEPs—Ergonomic Related	December 15, 2002 through March 31, 2003	50

Question. Specifically, how many hazard warning letters have been issued on ergonomic hazards, and how many general duty clause—5(a)(1)—citations have been issued?

Answer. Although many of the ergonomic inspections are still ongoing, those that have concluded have resulted in 88 ergonomic related Hazard Alert Letters (EHALs) (55 to nursing homes and 33 to establishments in other industries) and six 5(a)(1) citations for ergonomic hazards. Each EHAL recommends ways to reduce ergonomic hazards, and indicates that OSHA may conduct a follow-up inspection to assess the extent to which the employer has taken such action.

Question. Please provide a list of the establishments for which hazard warning letters or 5(a)(1) citations have been issued, and the date of their issuance.

Answer. Alpha Health Services, Inc. received three of the citations for hazards at three different facilities. Alpha Health Services was inspected under the NEP for Nursing and Personal Care Facilities. Other establishments receiving 5(a)(1) citations included Security Metal Products, which manufactures door frames; SuperValu; and Brown Printing.

OSHA is in the process of creating a list of the 88 establishments to which EHALs have been sent, including the date of issuance. Once we have created this list, we can provide it to the Committee.

Question. How many inspections on ergonomic hazards does OSHA plan in fiscal year 2003 and fiscal year 2004?

Answer. In general, OSHA does not have a pre-determined number of inspections under which we target ergonomics. OSHA's efforts are geared towards targeting establishments with the highest injury and illness rates. OSHA's Site-Specific Targeting Program focuses our inspection efforts on those employers who report the highest rates of injuries and illnesses. Because many of these injuries and illnesses are caused by ergonomic hazards, ergonomics will continue to be a focus of our inspections. Among the occupations with the highest numbers of days away from work were nurses' aides and orderlies. Under the current NEP for Nursing and Personal Care Facilities, we plan to inspect 1,000 nursing home establishments from September 17, 2002 through September 30, 2003. If this program is renewed, we will continue to focus on injuries that result from resident handling in nursing homes.

Question. To date OSHA has issued one final ergonomics guideline for the nursing home industry and announced that guidelines for 3 other industries (retail grocery, poultry and shipyards) will be developed. What is the schedule for the issuance of

these guidelines in proposed form and final form? What other ergonomic guidelines does OSHA plan to issue in fiscal year 2003 or fiscal year 2004, and what are the schedules for issuance of these guidelines?

Answer. OSHA published the nursing home guidelines less than a year after the announcement of the agency's four-pronged approach to dealing with ergonomics and after engaging in a public process that stressed stakeholder participation. OSHA has also released for public comment the draft retail grocery guidelines, and poultry processing guidelines. The agency intends to publish both of these guidelines in final form later this year. OSHA is working on the shipyard guidelines, and hopes to publish draft guidelines this fall with final guidelines completed early in 2004. The next topics to be addressed have not yet been determined but plans for additional guidelines will be announced in the next few weeks, as we complete work on draft guidelines for grocery stores and poultry processing.

OSHA STANDARDS

Question. One of OSHA's primary responsibilities is to set new safety and health standards to protect workers from injuries and illnesses. It is my understanding that there are several rules that have gone through the rulemaking process and are pending final action. These include rules on tuberculosis and employer payment for personal protective equipment. Both of these are important standards. The TB rule would protect health care workers not only from TB, but also other infectious agents like the new virus SARS. The payment for PPE rule would not impose any new requirements, but simply clarify that it is the employers' responsibility to pay for protective equipment provided by OSHA standards. This is particularly important for low-wage immigrant and Hispanic workers who are at increased risk of injury and death, who cannot afford to pay for their own protective equipment.

It is very disturbing that the Administration has repeatedly put off action on these two rules. Why has the Administration failed to act on these rules and when do you plan to issue the final rules on TB and Payment for Personal Protective Equipment?

Answer. In the current regulatory agenda, both the tuberculosis and employer payment for personal protective equipment (PPE) rulemakings were slated for a decision on the next step. We are continuing to review the records of both rulemakings. As appropriate, the agency will update the status of these and other rulemaking proceedings in the next regulatory agenda.

Question. What other proposed or final rules does the Administration plan to issue in fiscal year 2003 and fiscal year 2004, and what is the projected schedule for issuing these rules?

Answer. In fiscal year 2003, OSHA has issued proposals for: Commercial Diving Operations; Fire Protection in Shipyards; and Standards Improvement Project. During the remaining months of fiscal year 2003, proposals are expected to be published for: Assigned Protection Factors for Respiratory Protection; Controlled Negative Pressure Fit Testing Protocol; Vertical Tandem Lifts; General Working Conditions in Shipyards; and Electrical Safety. A proposal for Electric Power Generation, Transmission, and Distribution is currently in the SBREFA panel process, and should be published later this year. A proposal addressing Confined Spaces in Construction will also begin the SBREFA panel process soon.

OSHA has issued final rules for Exit Routes and parts of the Occupational Injury and Illness Recording and Reporting Requirements in fiscal year 2003. The agency expects to issue another final rule in fiscal year 2003 for Occupational Injury and Illness Recording and Reporting, as well as a final rule for Commercial Diving Operations.

With regard to fiscal year 2004, the current regulatory agenda does not provide commitments throughout that year. It is expected that final rules for Fire Protection in Shipyards and the Standards Improvement Project will be issued in the first quarter of fiscal year 2004.

Question. Last year as part of a reorganization of OSHA, the Directorate of Safety Standards and the Directorate of Health Standards were merged and the charge of the new combined directorate expanded to include the development of voluntary guidance. The proposed standard setting budget for fiscal year 2004 of $14.5 million is $1.6 million less than what was appropriated for standard setting in fiscal year 2003 ($16.1 million). Why are you proposing to cut the standard setting budget? What percent of the budget will be used to develop and issue mandatory standards and rules and what percentage will be used to issue voluntary guidelines?

Answer. OSHA's fiscal year 2004 budget for the Directorate of Standards and Guidance is sufficient to support the proposed regulatory agenda and develop other non-regulatory approaches to dealing with safety and health hazards.

The work involved in developing standards is similar to that involved in developing guidelines. As a consequence, the agency does not distinguish in its budget between standards development and the development of guidance materials.

OSHA ENFORCEMENT

Question. The Administration has proposed $165.3 million for federal OSHA enforcement for fiscal year 2004. While this represents a small increase in dollars over the fiscal year 2003 appropriated levels, it is not sufficient to maintain the number of FTEs budgeted in fiscal year 2003. How many FTEs for Federal enforcement are currently filled? How many are vacant? Please provide the number of FTEs and a list of the positions that will be eliminated if the Administration's fiscal year 2004 budget request for federal OSHA enforcement is adopted.

Answer. There are currently 1,603 employees filling positions in Federal Enforcement. OSHA has requested 1,581 FTE for Federal Enforcement for fiscal year 2004, a total of 31 less than the fiscal year 2003 authorized level. This reduction will not affect the number of safety and health inspections or the number of front-line OSHA enforcement staff. Consistent with the Department's workforce restructuring plans, which seek to streamline decision making processes and eliminate unnecessary overhead positions, OSHA proposes to eliminate field and national office positions that provide administrative and management support.

With the fiscal year 2004 Budget, OSHA has committed to achieving significant safety and health improvements—specifically a 5 percent reduction in the fatality rate, and an 8 percent reduction in the injury and illness rate. OSHA's proposed staff allocation enables it to meet those goals.

Question. In March, OSHA announced a new "Enhanced Enforcement" policy to focus attention on employers who were persistent serious violators of OSHA safety and health standards. Based upon agency press statements, it appears that this policy will consist largely of enhanced oversight. During previous administrations, including the Reagan and Bush I Administrations, OSHA instituted similar enhanced enforcement policies including the egregious policy which significantly increased penalties on egregious violators through the application of instance by instance citations and penalties.

Does the new enhanced enforcement policy include any provisions for enhanced citations or penalties? If so, what provisions are included? And if not, why aren't these employers being treated more severely with respect to citations and penalties than other employers?

Answer. Many of the specifics of the new Enhanced Enforcement Program are still being developed and will be embodied in a directive that OSHA will be issuing in the near future; they will, however, conform to the approach announced by the Secretary in March. The main intent of the program is to give OSHA a better targeting tool so we can focus resources on the employers who have shown the least regard for worker safety and health.

The new program will focus on employers whose inadequate attention to worker safety and health results in high-gravity citations. In these cases, OSHA will make sure that the employer's corporate headquarters receives copies of the citations. Additional inspections of workplaces affiliated with the same corporation will be more likely. When these employers choose to settle citations, we will use the settlement process to encourage the employers to implement systemic improvements to their safety and health practices. Finally, strong consideration will be given to Federal Court enforcement under Section 11(b) of the OSH Act. Although, in keeping with the law, the actual citation characterizations and penalty amounts will depend on the nature and circumstances of each violation cited, we will consider using all applicable OSHA sanctions, including instance-by-instance citations and penalties.

EXTENDED BENEFITS FOR AIRLINE INDUSTRY

Question. I was very disappointed to learn yesterday of the President's opposition to a temporary extension of unemployment insurance benefits to help unemployed airline industry workers who have lost their jobs. But I was heartened to see that 67 House Republicans joined all of the House Democrats to instruct the Appropriations conferees to help our workers.

As the Secretary of Labor, do you agree with the Administration that the government should provide billions of dollars in federal aid to ailing industries while doing nothing to support workers who have played by the rules, but have still lost their jobs?

Answer. The Administration has supported two federal extensions of unemployment benefits to workers who have not been able to find new jobs before exhausting regular state unemployment benefits. While we have concerns about providing a

more generous level of benefits to workers in a particular industry, the Administration will continue to work with Congress to determine how these workers can be assisted in finding reemployment.

EXTENSION OF UNEMPLOYMENT COMPENSATION

Question. If economic conditions do not rebound by the summer will you support an extension of unemployment compensation benefits to allow additional time for job growth to occur?

Answer. The President and I are focused on job creation. The Administration proposed a Jobs and Economic Growth Plan, including tax relief and Personal Reemployment Accounts, to provide meaningful stimulus for the economy. Additionally, we will work with the Congress to help unemployed workers who have exhausted their benefits before finding new jobs.

TRADE ADJUSTMENT ASSISTANCE

Question. In the letter Mitch Daniels sent to Congressional Appropriations leaders yesterday, he said the White House opposed the Murray airline workers amendment because, "To provide benefits for a specific industry would be unusual, unfair and potentially harmful to our national unemployment system."

Is it the Administration's position that Trade Adjustment Assistance which provides benefits to specific industries is also unusual and unfair?

Answer. The Trade Adjustment Assistance Program does not provide benefits to specific industries. The program is not industry-based and is available to any worker group impacted by foreign trade.

Worker groups in virtually all industries have been certified for TAA benefits at one time or another. Workers whose firms are adversely affected by increased imports or a shift in production to a country which has a free trade agreement with the United States or a country under certain specified Acts are potentially eligible for TAA certification. Further, workers who are found to be secondarily-impacted, as defined in the Act, may also be eligible.

MIGRANT AND SEASONAL FARMWORKERS ELIMINATION

Question. It appears that the Department no longer believes that a national program for migrant and seasonal farm workers is needed.

How will we avoid burdening Governors and local One-Stops with the responsibility of trying to serve workers who may work and reside in their states for brief periods during this time of huge and growing state deficits?

Answer. The Workforce Investment Act (WIA) created the federally-funded One-Stop Career Center system, designed to provide an integrated system of workforce investment services at the local level and to provide universal access to these services for all customers. The Administration's fiscal year 2004 budget proposal seeks to tap the system's potential to serve more migrant and seasonal farmworkers by providing job training services for them through the One-Stop delivery system and turning to other appropriate agencies to provide social and supportive services, housing, and other related assistance.

To facilitate the transition, we have been working with the current National Farmworker Jobs Program (NFJP) grantees to identify initiatives that can be undertaken to support the One-Stop delivery system's efforts to be responsive to farmworkers. We are considering pilot and demonstration projects to test new ways to increase farmworkers' employment and earnings, and training and technical assistance to states and localities to meet the challenge of providing universal and effective workforce services.

We believe that workforce investment services organized through the One-Stop delivery system play a vital role in building strong local economies, and that providing services to farmworkers through the One-Stop delivery system will increase the number served and have a positive employment and earnings impact on those who receive services.

ASBESTOS TAINTED VERMICULITE

Question. I remain concerned that workers across the country are still being exposed to unacceptably high levels of asbestos. I am particularly concerned that workers are being exposed to asbestos-tainted vermiculite, which may still be in as many as 35 million homes.

Do you believe OSHA and EPA need to do more to warn workers and homeowners not to disturb this product?

Answer. Since OSHA's inception in 1971, the agency has used its authority for standard-setting, enforcement, and compliance assistance to protect workers from the threat of asbestos.

In addition to the final asbestos rule issued in June 1972, the agency issued two subsequent emergency standards, the last of which published two final asbestos standards, one for general industry and one for construction; added shipyards as a covered industry; and lowered the PEL to 0.1 fibers per cubic centimeter. All employers are required to communicate information about asbestos hazards to all potentially affected employees at a worksite.

OSHA enforces the current asbestos standard through routine, random or targeted inspections. Many of the several thousand inspections conducted by Federal or State OSHA programs, in which violations of the standard were cited, were initiated as a result of employee complaints and referrals from Federal or State agencies.

OSHA provides compliance assistance to employers and employees to help them understand the dangers of asbestos, and how to minimize or eliminate the threat. OSHA's Web page connects computer users to concise and easy-to-read publications on asbestos, which are available to the public free of charge. Pamphlets explain the requirements of the standards for both general industry and construction. Included in each is a list of sources of assistance. OSHA's Web page also includes reports, links to other Web sites, slides, and information about taking samples and controlling exposure to asbestos. OSHA offers an intensive course covering the recognition and control of asbestos at its Training Institute in Illinois.

OSHA has also developed software that can be downloaded from its Web site to provide interactive expert advice for building owners, managers and lessees, as well as for contractors of building renovation, maintenance and housekeeping services. Once installed on a computer, the software asks questions about a building site. It then asks follow-up questions based on answers, and produces a report on responsibilities under the asbestos rules.

In all 50 states, OSHA's free on-site consultation program is available and provides expert assistance on asbestos to small businesses.

CUTS IN EMPLOYMENT AND TRAINING SERVICES AND GAO

Question. In the past, you have argued that cuts in employment and training services can be accomplished without impacting service delivery because of a carryover of funds in WIA formula programs.

The General Accounting Office (GAO) recently conducted an investigation and found that the Administration's argument was not accurate. It said, "Our analysis of Labor's data shows that states are rapidly spending their funds—in fact nationwide states have spent 90 percent within 2 years, even though the law allows 3 years to spend the money." In fact, my state was found to have spent 98 percent of their formula funding in fiscal year 2001.

Would you now agree that cuts in funding will mean cuts in services?

Answer. Absolutely not. The President's 2004 Budget and the Administration's WIA reauthorization proposal not only would maintain, but allow for increases in, job training participation. As the Assistant Secretary for Employment and Training said in the Department of Labor's (DOL) February 7th response to GAO's report, DOL does not dispute that states are exceeding the minimum requirements for spending under the Act. However, DOL and the Administration believe that it is important to look beyond the minimum expectations when making these workforce investment decisions. The Department has never questioned whether these funds will be spent over time. What concerns us is the amount that is carried over from one program year to the next that could have been used for program services during the year for which the funds were appropriated. For the past few years, large and record-level amounts of WIA state grants have remained unspent and in the Treasury at the end of the year. For fiscal year 2004, these balances still will be an estimated $1.7 billion. So, while the state under-spending problem has improved somewhat, the fiscal year 2004 budget request takes into account these continuing large amounts of unexpended carry-over funds.

—The recent GAO report (GAO–03–239) found that states are spending their WIA funds much faster than required under the law. However, our own analysis of state spending data indicates that spending rates of available funds continue to increase only marginally as state programs become more established and financial reporting procedures are improved.

—Despite improved spending rates, there remain large amounts of state unexpended carryover funds from the previous two years that compel us to prudently keep our fiscal year 2004 budget request at roughly the fiscal year 2003 levels.

This budget would provide adequate funding to maintain and even increase services in the coming year. Any need for additional funding in local communities can be addressed within the flexibility of other provisions in WIA.

—Further, the Administration's fiscal year 2004 job training policy provides new authority to the Secretary and states to reallocate funds to the few states and localities that have exhausted the resources available to them. The Administration proposes to recapture funds from states with more than 30 percent of all funds that were available for expenditure during the prior program year (including carry-in funds from previous years) that remain unexpended, compared to the current law provision which only recaptures funds from states with more than 20 percent of funds from the prior program year's allotment that remain unobligated. The proposal more directly targets areas where there are significant levels of under-spending.

PERSONAL REEMPLOYMENT ACCOUNTS

Question. The President's Economic Stimulus package proposes to spend $3.6 billion on a new untested program called Personal Reemployment Accounts. This proposal has received criticism from the workforce community and Republicans and Democrats in the Congress.

Given the unlikely enactment of this new scheme by the Congress, why not use this money to more adequately fund programs for adults, youth and dislocated workers that are part of the already well established Workforce Investment Act?

Answer. The President's 2004 Budget and the Administration's WIA reauthorization proposal not only would maintain, but allow for increases in, job training participation. The concept of the Personal Reemployment Accounts (PRA) initiative, and particularly its elements of greater flexibility and customer choice, are important to the President and considered key to the success of today's unemployed workers in reattaching to the labor market. Even if the Congress fund the PRA initiative, the Administration proposes to offer PRAs as a service option using funds available through a reauthorized Workforce Investment Act (WIA).

WIA FORMULA AMENDMENTS

Question. Last week DOL's Employment and Training Administration (ETA) released the state formula allocations for fiscal year 2003 for the WIA formula funded programs. Despite having the second highest state unemployment rate in the nation Washington received a cut of over $33 million in its WIA formula funds, with most of the reduction ($29 million) coming in the dislocated worker account.

Clearly the Workforce Investment Act (WIA) formula factors do not accurately reflect current economic conditions in a state.

Madame Secretary, will you work with me during the reauthorization of WIA to develop formula factors that more accurately reflect and are responsive to current economic conditions in a state?

Answer. Yes. We are aware the current statutory formulas are outdated and are hopeful that changes will be made as part of the WIA reauthorization process. The Administration's reauthorization proposal consolidates three funding streams (Adult, Dislocated Worker, and Employment Services) into a single comprehensive funding stream designed to provide services to adults. Under current law, funds under each of the three separate streams are distributed according to specific statutory formulas based on a range of factors (such as unemployment, civilian labor force, etc.).

The Department recognizes a need to develop a new formula. The development of a new formula is also consistent with a recent GAO study that found that the current statutory language dates back to programs run in the 1970s and are outdated and inconsistent with current programmatic goals. Under the Administration's recommended formula, states will no longer experience the dramatic funding swings that currently exist from year to year under the Dislocated Worker program.

YOUTH PROGRAM CUTS

Question. Why is the Administration proposing to cut youth formula training programs, which currently serve less than 10 percent of the eligible youth and to phase out the Youth Opportunity Grant (YOG) program, which provides at-risk youth education and training opportunities in high poverty areas, at a time when research has shown that nearly 50 percent of those Americans who have lost their jobs over the last two years are under 25 years of age?

Answer. Proposed funding for youth programs under WIA is $1 billion for fiscal year 2004. The proposal targets resources to those youth most in need of assistance to reconnect to the education and workforce systems-specifically school dropouts and

other out-of-school youth who are basic skills deficient. Seventy-five percent of the funds will be allocated by formula to the states to serve out-of-school youth. This program will provide services that have proven effective in assisting such youth. Our youth investments will focus on providing young people with a strong, core academic foundation in conjunction with post secondary skills, certifications or degrees, and transitions to career path employment

It may be noted that the remaining 25 percent will be reserved for national Challenge Grants, which may be used for a number of activities to assist youth in acquiring the skills, credentials, and employment experience necessary to succeed in the labor market. Those grants could include services to some at-risk in-school youth. However, the primary purpose of the revised youth program is to target resources to out-of-school youth who are currently underserved and most in need of the assistance the WIA youth program can provide.

The Youth Opportunity Grants were five-year demonstration grants and every grantee received their five-year commitment. Although we currently do not have outcome results, we intend to use lessons learned from the Youth Opportunity Grant initiative and other demonstrations in designing the new Challenge Grants. We will incorporate proven strategies and build upon the positive features of the Youth Opportunity Grants while addressing problems of the program. For example, we will seek to increase the current 15 percent diploma rate for out-of-school youth. Other improvements include greater private sector involvement, and enhanced coordination with other local agencies, including community and faith-based organizations.

YOUTH OPPORTUNITY CUTS

Question. If you do not support the Youth Opportunity Grants because it is a discretionary grant program targeted to 30–40 communities, why are you asking Congress to fund a new, untested Youth Challenge Grant Program that will be targeted to a small number of sites, while reducing the youth formula funding by 25 percent ?

Answer. The Administration will build on the lessons learned in Youth Opportunity Grants as we implement the new Challenge Grants. We believe that we will be improving on Youth Opportunity Grants and other past investments in several ways. First, there will be much stronger private sector involvement. Second, matching requirements will result in stronger local ownership and commitment to the program because DOL will require matching resources. Third, there will be more of an emphasis on placement and training in demand occupations. Fourth, there will be an emphasis on strategies of demonstrated effectiveness in the areas of improving educational and labor market outcomes.

The Administration's WIA proposal reserves 25 percent of the youth activities appropriation for Youth Challenge Grants, 80 percent would be available for competitive grants and 20 percent would be available for discretionary grants. Generally, competitive grants will be aimed at geographic areas of substantial need, and discretionary grants will be awarded to programs of demonstrated success.

The purpose of the competitive grants is to promote collaboration and innovation in providing activities to assist youth in acquiring the skills, credentials, and employment experience necessary to succeed in the labor market.

The competitive grants may be awarded to States, local boards, recipients of Native American program grants, and public or private entities (including consortia of such entities) applying in conjunction with local boards. Initial awards would be made for one year, with four additional years available depending upon satisfactory progress and availability of funds. The Secretary would be authorized to require that grantees provide a nonfederal share of the cost of activities carried out under a grant, and may require that such share be provided in cash or noncash resources.

Youth ages 14 through 19, as of the time the eligibility determination is made, may be eligible to participate in activities provided under these grants. Funds would be used for the activities to assist youth in acquiring skills, credentials, and employment experience, including training and internships in high-growth sectors for out-of-school youth; after-school dropout prevention programs for in-school youth; activities to assist special youth populations, such as court-involved youth and youth with disabilities; and activities combining remediation of academic skills, work readiness training, and work experience, and including linkages to postsecondary education, apprenticeships, and career-ladder employment.

To be eligible, an entity must submit an application to the Secretary that includes a description of the activities the eligible entity will provide to eligible youth; a description of the programs of demonstrated effectiveness on which the provision of the activities are based, and a description of how such activities will expand the

base of knowledge relating to the provision of activities for youth; a description of the private and public, and local and State resources that will be leveraged to provide the activities described; and the levels of performance the eligible entity expects to achieve with respect to the indicators of performance for youth.

Factors to be considered in awarding these grants include the quality of the proposed project, the goals to be achieved, the likelihood of successful implementation, the extent to which the project is based on proven strategies or the extent to which the project will expand the knowledge base on activities for youth, other Federal and non-Federal funds available for similar purposes, and the additional State, local or private resources that will be provided.

In addition, discretionary grants for youth activities would be authorized that will assist youth in preparing for, and entering and retaining, employment. These grants are intended to provide the flexibility to assist a variety of entities and organizations in providing innovative and effective activities for eligible youth, including special populations. The Secretary may award discretionary grants to public or private entities that the Secretary determines would effectively carry out activities relating to youth.

The Administration believes these grants would provide enhanced opportunities to replicate proven strategies in assisting youth and to apply such strategies in innovative ways.

ELIMINATION OF H–1B

Question. The skills gap in this country keeps growing wider. The training component of the H–1B program, which represents a key investment in American workers, is set to expire this year. The GAO issued a report this fall which said the program is meeting specific workforce needs. Despite this positive report your Department is not seeking reauthorization for the program, but is seeking additional funding to process alien certification applications from foreign workers.

Should the Labor Department be expediting the importation of more foreign labor into this country, while refusing to support proven high skills training for American workers?

Answer. The Administration is committed to job training in skill shortage occupations as a key element of all of the job training programs administered by the Department, including the formula programs administered by States and local areas under title I of WIA.

In addition to providing training linked to occupations in demand under WIA, TAA and other employment and training programs, the Department of Labor will continue to make approximately $200 million in collected employer fees available for H–1B Technical Skills Training Grants until the funds collected as the employer fees for this program are fully expended. The authorization for that program expires September 30, 2003.

The Department also administers the labor certification requirements of the work-based permanent immigration and temporary visa programs and attempts to do so in a timely and effective manner. The 2004 Budget funds the first part of a two-year effort to eliminate unacceptable backlogs that have grown under the permanent program in recent years while, in 2003, the Department will implement reforms in the program to help eliminate future backlogs. Effective, efficient processing of labor certification applications for the H1–B and other programs meets the legislative intent to protect jobs for American workers while responding to employers' legitimate need for staff to meet limited skill shortages.

ONE STOP INFRASTRUCTURE

Question. When I visit local One-Stop Career Service Centers in my state the first question that workforce managers ask is, "Why can't the federal government reinstitute a dedicated One-Stop infrastructure funding stream to assist in real estate acquisition, management information system updates, staff development and other non-service delivery issues?"

Madame Secretary, how do you answer that question?

Answer. Through WIA reauthorization, the Department proposes that part of the operational cost of the certified One-Stop centers be financed through dedicated "One-Stop infrastructure" funding. Each partner program would contribute a portion of their funds to the Governor to be allocated for One-Stop infrastructure funding in the State. This approach would create a greater sense of partner "ownership" of the system than currently exists and would move toward comprehensive workforce system reform by using existing dollars to support an integrated service delivery system at the state and local level.

The portion of funds to be provided by each One-Stop partner would be determined, subject to certain limitations, by the Governor after consultation with the State board, which includes representatives from the One-Stop partner programs. In making the determination regarding the funds to be contributed, the Governor would be required to consider the proportionate use of the One-Stop Career Centers by each partner, the costs of administration unrelated to the use of the One-Stop Career Centers by each partner, and other relevant factors that are also to be considered in developing the allocation formula for these funds, such as the number of certified One-Stop Career Centers in the local area, the services provided by the centers, and other factors relating to the performance of the centers.

In those States where the State constitution places policymaking authority in an entity or official that is independent of the authority of the Governor for the adult education and literacy program under title II of WIA and postsecondary vocational education program under the Carl D. Perkins Vocational and Technical Education Act of 1998, the Governor would make the determination of the funds to be contributed by those programs with the entity or official that has the independent authority.

In addition, the funds provided by the One-Stop partner programs for the infrastructure costs are to be provided from funds available for administrative costs under each program, and those funds are subject to whatever administrative cost limits are applicable to each program. There would be a specified limit for the contributions that may be required of the Vocational Rehabilitation program of 0.75 percent of the funds provided for such program to the State for a fiscal year. There would also be a limitation that the contributions required of Federal direct spending programs (such as TANF, the Child Support Enforcement program, and the Food Stamps Employment and Training program) may not exceed the amount equal to the proportionate use of the One-Stop Career centers by those programs.

The formula for allocating these funds to the local areas for the certified One-Stop centers would be developed by the State board, including factors such as those described above. The infrastructure funds would be used to pay for the non-personnel costs that are necessary for the general operation of the certified One-Stop Career centers, including the rental costs of the facilities, the costs of utilities and maintenance, and equipment (including adaptive technology for individuals with disabilities).

While the infrastructure funding would address the primary common costs of operating the One-Stop Career Centers, there would remain some common costs that would not be covered by these funds. These additional common costs would be funded using the procedures that currently apply to all operating costs and the provision of core services. The partners would provide funding or noncash resources, to cover the costs of providing the core services that are applicable to the participants from each program and other common costs, such as infrastructure costs in excess of the amount provided by the new infrastructure grants, and other common costs not included in the infrastructure definition (such as personnel). The local memorandum of understanding among One-Stop partners would remain the vehicle for determining these common costs and how to allocate these costs since these costs would be more locally variable. The State board would provide guidance to facilitate the determination of appropriate funding allocation in local areas

ELIMINATION OF EMPLOYMENT SERVICE

Question. The U.S. Employment Service provides a nationwide public labor exchange for all workers and employers.

With the proposed elimination of the Employment Service, how does the Department expect 50 states to carry out this national purpose without compromising or undermining the principles of universal access and a free, public, national labor exchange?

Answer. The job search assistance services provided under the Wagner-Peyser Act are also required to be provided as a core service for all adults under the WIA Adult program and for all dislocated workers under the WIA Dislocated Worker program. All three programs are to make these services available through the One-Stop delivery system established in each local area under WIA. Rather than have these overlapping and duplicative requirements for the provision of these labor exchange services under three different programs, the Administration believes the three funding streams should be consolidated into a single, comprehensive program for adults which includes as a key element the availability of universal public labor exchange services for all job seekers and employers. Rather than undermining or compromising the principle of universally accessible labor exchange services, the Adminis-

tration believes the proposed consolidation would strengthen and enhance the provision of those services.

FAIR LABOR STANDARDS ACT

Question. The Department's decision to abandon the two-tiered salary test, which provides greater protections to salaried workers with lower earnings than to those who earn more, makes it easy for an employer to manipulate job duties in order to deny overtime protection to many low-wage earners. How does the DOL justify a proposed salary threshold that will allow employers to deny overtime pay to many who need and rely on it?

Answer. The Department has not abandoned the two-tiered salary level tests, and the Department's proposed salary threshold will not deny overtime pay to employees who need and rely on it. To the contrary, the Department's proposed regulatory changes will increase overtime protections for 12 million employees—including an additional 1.3 million low-wage salaried workers who will be guaranteed overtime protections for the first time.

The current regulations establish two different salary levels for each of the exemption categories: Employees paid below the minimum salary level of $155 a week are not exempt from overtime regardless of their duties. Employees paid above the minimum salary level of $155 a week are only exempt if they meet the "long" duties test. Employees paid above a higher "upset" salary of $250 a week are exempt if they meet a "short" duties test.

The Department has long recognized that salary level may be the best indicator of whether an employee is a bona fide executive, administrative or professional employee. Because the salary levels have not been raised in 28 years, since 1975, the existing salary levels have become meaningless. Under the current minimum salary level of $155 a week, only employees who make less than $8,060 a year are guaranteed overtime pay. By contrast, a minimum wage employee who works 40 hour a week earns over $10,700 a year. Thus under the current regulations, a minimum wage employee can be classified as an exempt executive. This perverse result demanded action by the Department of Labor.

The Department's proposed regulations would raise this minimum amount to $425 a week, or $22,100 a year—a $270 a week increase and the largest increase in the 65 year history of the FLSA. The largest prior increase was by only $50 a week. As in the current regulations, employees who earn less than this minimum salary level are guaranteed overtime pay. This increase in the minimum salary level will guarantee overtime pay to 1.3 million additional low-wage workers.

Under the Department's proposal, similar to the current regulations, employees earning more than $425 per week can only be classified as exempt if they also meet a "standard" duties test. The proposed standard duties test would streamline the current regulations by replacing the separate "long" and "short" duties tests with one test representing a middle ground between the current long and short tests. The Department believes this change will make the regulations easier for both employees and employers to understand who is entitled to overtime pay under the FLSA.

Although the proposal replaces the "long" test and "short" test terminology, the proposal does not eliminate the two-tier salary structure. As noted above, the current regulations contain a "special proviso for high salaried" employees (see, e.g., § 541.119)—the so-called "short test"—which currently requires a salary of only $13,000 a year. The Department's proposed special provision for higher compensated employees would require guaranteed compensation of $65,000 a year. The Department has proposed to minimize the duties requirements that must be met before an employee earning more than $65,000 a year may be classified as exempt. However, the $65,000 annual guarantee is well above the current $13,000 requirement. The $65,000 annual guarantee is also well above the $43,000 salary level requested by the AFL–CIO in a letter to the Department as the increase necessary to fully correct the current $13,000 level for inflation since 1975.

The Fair Labor Standards Act was intended to set minimum salary and overtime standards to protect the most vulnerable, low-wage workers in our society. Because so many years have passed since the Department updated the Part 541 regulations defining exempt executive, administrative and professional employees, the protections intended by the FLSA have been severely eroded. The Department's proposal will strengthen minimum wage and overtime guarantees for the low-wage workers the FLSA was designed to protect. In addition, by simplifying and clarifying the rules, the proposed regulations will allow the Department to more strongly enforce the FLSA minimum wage and overtime provisions. The Department expects and welcomes public comment on the proposed salary levels and proposed duties tests.

LM–2 FINANCIAL DISCLOSURE

Question. Under your LM–2 financial disclosure proposal, a labor organization would have to itemize every disbursement made to an entity or individual that reaches a threshold of between $2,000 and $5,000 in one of eight categories. The organization also would have to itemize aggregate disbursements to an entity or individual that reach this threshold over the reporting period. Within these parameters, I am advised that it would not be unusual for a medium-sized union to report 9,000 individual disbursements during a given year. Add to that separate disbursements that aggregate to $2,000 and the potential exists for a significant amount of numbers to report.

How would this then practically conform with 67 Fed. Reg. at 79281, that the reported information provide "union members with useful data that will enable them to be responsible and effective participants in the democratic governance of their unions?" Will this information be useful to union members?

Answer. The Department received many comments regarding the itemization thresholds and we are still reviewing those comments. When that review is completed, we hope to be better able to address these questions. The proposal, however, was based upon certain facts that may be helpful in understanding the likely impact of an itemization requirement, if it is adopted. For example, it should be noted that the median LM–2 filer has approximately $650,000 in annual receipts. Assuming that the annual receipts of a union are roughly equal to its annual disbursements, and if $2,000 itemization threshold were adopted, a union with $650,000 in disbursements is likely to have no more than 325 itemized transactions. In practice, however, the number of itemized transactions would actually be lower because a number of transactions are likely to be more than $2,000. Moreover, not all disbursements will be subject to itemization. If roughly half of all disbursements fall into categories that would not require itemization these unions might have to itemize fewer than 150 disbursements per year. If a $5,000 itemization threshold were adopted, an average union might have to report less than 60 itemized transactions.

For the average LM–2 filer union, that has approximately $2.8 million in annual receipts, and a roughly equivalent amount in annual disbursements, a $2,000 itemization threshold would be likely to require the reporting of less than 650 itemized transactions. If a $5,000 itemization threshold were adopted, a union with $2.8 million in disbursements might only have to report less than 260 itemized transactions. Less than 675 unions, or just 2.3 percent of all unions and 12.4 percent of all LM–2 filers, have annual receipts of $3.0 million or more.

Even in those cases where there may be many itemized transactions, not all commenters agree that union members will not find the information useful in any event. The proposed LM–2 contains summary data in aggregate categories that reflect the services performed by unions for their members so that union members would continue to be able to assess the overall status of the union by looking at just a couple of pages. In addition, the Department's proposal indicated that the requirement that these reports be filed electronically would make it easier to provide union members with easy access to detailed information regarding the major transactions of their union by using an online, searchable database that will display only those transactions of interest to the member. The intent of the Department's proposal is to better enable union members to judge the financial health and integrity of their unions and to hold their leaders accountable for the financial condition of their union.

Question. Additionally, unions would have to itemize their officers' and employees' salaries. How is this information useful to union members?

Answer. Officers' and employees' salaries have always been itemized or individually reported on the forms; the law requires it. Although the proposed salary schedules would require the salaries of officers and employees to be allocated to the appropriate disbursement categories, to reduce reporting and recordkeeping burdens the Department has proposed that officers and employees be allowed to estimate their time to the nearest 10 percent, rather than requiring them to make exact calculations and keep daily records of their time. Because salaries are often the largest disbursement for many unions, the Department proposed this requirement to improve the transparency and accountability of labor organizations to their members and better enable them to exercise their democratic rights of self-governance.

Question. Mandatory electronic filing is at the heart of your proposal. As I understand it, the computer software is what will make it financially possible for labor organizations to comply with the new disclosure requirements. However, I am advised that this software does not yet exist.

Will you complete development of this software before requiring unions to comply with the proposed regulations? Can the proposed regulations be promulgated prior to development of the software?

Answer. The purpose of the software is to reduce the reporting burden on unions and to reduce the cost of disseminating the information on the Internet to union members. It is important to note, that the software to be provided by the Department is not a bookkeeping system. The software has no impact on the burden of collecting data for the LM–2. The implementation of the reporting software will come in two phases. First, the Department will provide a Data Specifications Document before the effective date of the reform that will give unions the information they will need to interface with the software and report their information to the Department electronically. The Department is also going to establish a help line to answer any questions and will make other compliance assistance available. Second, the software will be provided to the unions well before they will have to use it to file their report, which will give the Department plenty of time to conduct compliance assistance and answer questions posed by the filing community. Moreover, all of the information that unions will need to update their internal recordkeeping and reporting requirements for the proposed Form LM–2 will be contained in the final rule that is published in the Federal Register.

Question. In your response to my April 2, 2003, letter, you cite the finding of a 1998 hearing of the House Education and Workforce Subcommittee on Oversight and Investigations that "the current LM–2 Form is inadequate to prevent and uncover financial corruption, and the form should therefore be substantially revised."

How does requiring unions to itemize most of their expenses deter fraudulent activity?

Answer. Increased transparency and disclosure is a natural deterrent to criminal activity and financial mismanagement. The more detailed information is reported regarding specific transactions, the more difficult it is for an unscrupulous person to conceal their activities and the easier it is for union members and the Department to uncover fraudulent activity. Again, the intent of the Department's proposal, including the proposed itemization requirement, is to help meet the objectives of the statute by providing union members with useful data that will enable them to be responsible and effective participants in the democratic governance of their unions. As Representative Robert Griffin, a cosponsor of the LMRDA, stated: ". . . [I]n a larger sense, the effectiveness of the Act will depend also upon the rank-and-file union members themselves. For in the last analysis, it is they who must make the law meaningful by taking hold of the tools of democracy and using them to clean corruption out of their unions and to keep them clean."

Question. Has the Department considered requiring unions to undergo independent audits, as are SEC regulations currently require of public corporations?

Answer. Yes, the Department has considered requiring audits. Some commenters suggested requiring audits; the Department is currently reviewing those comments and has not yet reached any final conclusions. It is important to note, however, that the laws enforced by the SEC are very different from those enforced by DOL.

Question. In your response to my April 2, 2003, letter, you note that "most of the Department's proposed changes affect only the largest 20 percent of unions subject to the Labor Management Reporting and Disclosure Act."

How would the proposed changes affect the smallest of those unions subject to the reporting requirements? Has the Department assessed what the cost would be for those unions to comply, particularly those which marginally exceed the $200,000 threshold? Has the Department taken any steps to minimize the cost to smaller unions?

Answer. The Department is always conscious of the regulatory burden imposed on smaller entities. The smallest unions, over 81 percent of all labor organizations would not be affected by most of the reforms proposed. The Department's proposal would require all unions to file a new Form T–1 to report financial information for large trusts or other funds in which they have an interest, but only if the union contributed $10,000 or more to the trust during the year. The Department has received comments arguing that this requirement should be dropped, as well as comments arguing that all of the proposed changes should be applied to all unions. The Department has not yet made a final decision on any of these issues.

The Department also requested comments on whether the filing threshold should be raised from $200,000 to adjust for inflation and those comments are being considered. The Department has estimated the costs for various sizes of LM–2 filers and the burden estimates were calculated as weighted averages of those groups of unions. Under the proposed rule the average burden for the smallest group of LM–2 filers for the first three years would be 81.7 percent less than the burden for the largest group of LM–2 filers.

The Department's proposal also included many features to minimize the burden. First, the proposed levels of itemization of disbursements would ensure that small unions would have to identify very few transactions. For instance, a $2,000 itemization threshold is likely to require a union with $250,000 in disbursements to itemize less than 60 transactions and a $5,000 threshold is likely to require a union with $250,000 in disbursements to itemize less than 25 transactions. Second, the filing software is being designed to fit the needs of the unions, so that small LM–2 filers will be able to simply type information in the forms or copy-and-paste, whereas larger LM–2 filers will be able to take advantage of greater automation and download information directly into the software. Finally, a union can apply for and be granted a hardship exemption to allow them to file a paper report if they can demonstrate that electronic filing would impose an unreasonable burden.

Question. Has the Department consulted with the Small Business Administration Office of Advocacy to determine whether the proposed rules are in compliance with the Regulatory Flexibility Act of 1980 as amended (5 U.S.C. 601–612)?

Answer. Yes. The Department took all required steps to ensure that the proposal is in full compliance with the provisions of the Regulatory Flexibility Act of 1980 as amended, and consulted informally with the SBA.

Question. Has the Department considered drafting different regulations that reflect the different sizes of unions subject to compliance under the Labor Management Reporting and Disclosure Act?

Answer. Yes, the Department's regulations already permit smaller unions to file simplified forms LM–3 and LM–4. Additionally, the Department took the concrete steps described above in the proposed rule to limit the burden on smaller LM–2 filers and is reviewing comments that it sought on whether the current $200,000 threshold for Form LM–2 filers should be raised to $250,000 or some other amount, or, instead, whether it should be left unchanged.

Question. Do you believe that the 90-day comment period for these proposed regulations was sufficient? Did your Department consider extending this period to fully accommodate suggestions and criticisms by those organizations that would be affected by the proposed regulations?

Answer. Yes, the 90-day comment period was sufficient. The Department carefully considered all requests for an extension of the 60-day comment period, and a 30-day extension was granted. The Department received nearly 36,000 comments, including many substantive comments from unions, non-profits, and others, indicating that 90 days was a sufficient period of time to comment on the rule. This timeframe is also consistent with other major rulemakings of the Department and other federal agencies.

Question. In your response to my April 2, 2003, letter, you indicate that "the regulatory regime governing financial reporting by small and large public companies is much more extensive than the system that exists for labor organizations." You then note that "Government Accounting Office regulations governing accountability for federal funds mimic the extensive system of regular audits, extensive internal controls and disclosure of material qualitative and quantitative data that exist for publicly-traded companies."

I have been advised that some of the proposed LM–2 requirements mandate more extensive itemization of information than is required by the SEC under the Sarbanes-Oxley Act of 2002 and by the GAO. For example, under current LM–2 requirements, labor organizations subject to compliance are required to list all employees whose total salaries, allowances, and other direct and indirect disbursements from the union exceed $10,000 per year; the union must also detail the employees' position, affiliated organization, gross salary, allowances and disbursements. The proposed changes would additionally require that labor organizations report for each employee his or her net salary, withholding and direct taxes, disbursements for other withheld amounts, direct payroll taxes, and allocation of each employee disbursements into new functional categories. The SEC does not require this level of detailed information, only requiring salary information for top executives. Given your above statement, how do you explain this disparity between LM–2 and SEC reporting requirements?

Answer. The laws and regulations governing corporations and unions serve very different purposes and are understandably quite different. The LMRDA established a unique financial disclosure regime for labor organizations designed to address concerns about unions that were highlighted by Congressional hearings on financial and other misconduct in labor unions. To the extent that a comparison is relevant, the regulatory regime governing financial reporting by small and large public companies is much more extensive than the system that exists for labor organizations. In addition to mandating the disclosure of certain types of quantitative data, the financial reporting scheme for public companies, as amended by the Sarbanes-Oxley

Act, also requires the disclosure of qualitative information and imposes strict audits and detailed internal controls on public companies, their officers, directors, auditors, accountants and attorneys.

The SEC only requires reporting of the salaries of "top executives" because that is what their statute mandates. OLMS requires reporting of the salaries of all officers and employees earning $10,000 or more annually from the union because that is what our statute mandates. As for the specific information collected in the salary schedules, it would be inappropriate to discuss our specific views because the Department is in the process of analyzing and responding to the comments we received from the public on the NPRM. In general, the Department believes that the details contained in the LM–2 will be useful to union members and will fulfill the statutory requirements of the LMRDA. The SEC would have to respond to whether this sort of disclosure would be appropriate and useful under the statutes they enforce.

Neither the current LM–2 reporting regime nor the Department's proposed rule require labor organizations to provide their members with any qualitative information, much less the detailed analysis public companies are required to disclose. Federal law also does not mandate that unions use governance structures that ensure independent oversight of financial operations, such as independent audit committees and union members have no comparable whistleblower rights to those provided employees under the Sarbanes-Oxley Act. Unions are not currently required, nor would they be required under the proposed transparency reforms, to provide any qualitative information to their rank-and-file membership about the financial health of their union, the strengths or weaknesses of any substantial investments by their union, the financial performance of any programs, contracts or cost centers managed by the union, or any future risks associated with the union's business relationships, including its main bargaining unit employers, membership composition or other factors. Considered in this context, the Department does not believe that the proposed LM–2 is overly burdensome when compared to corporate disclosure.

QUESTION SUBMITTED BY SENATOR THAD COCHRAN

FARMWORKER HOUSING

Question. The fiscal year 2003 Omnibus Appropriations bill includes $4.64 million for Department of Labor Farmworker Housing activities. In recent years, the Appropriations Committee has directed the Department of Labor to use these funds to continue the long-established network of local housing organizations working to plan, develop, and manage housing for migrant and seasonal farmworkers.

What is the status of fiscal year 2003 funds, how will they be made available, and what steps are the Department taking to ensure that the current network of organizations remains in place?

Answer. The $4.64 million pre-rescission appropriation for farmworker housing assistance grants is being awarded through an open competitive grants selection process. The Employment and Training Administration (ETA) recently published the Solicitation for Grant Applications (SGA) for the housing assistance grants and an SGA for the National Farmworker Jobs Program (NFJP) in the Federal Register, and the application period will close on May 16, 2003, and the awards will be announced before June 30, 2003.

Every proposal submitted in response to the SGA, including those from current grantees, will be given full and fair consideration. They will be reviewed and rated on their merit by an impartial review panel.

QUESTIONS SUBMITTED BY SENATOR ERNEST F. HOLLINGS

ASSOCIATION HEALTH PLANS

Question. I would like to know how much Congress must appropriate for the Labor Department to effectively regulate Association Health Plans, if legislation to exempt them from state oversight is enacted. In 1997, Olena Berg, Assistant Secretary of Labor in the Clinton Administration, said that DOL did not have the resources to regulate AHPs and that it would take 300 years to complete a review of each existing pension and health plan. A recent GAO report found that it would take DOL's current investigative staff 90 years to do a baseline assessment of noncompliance for pension plans alone. An analysis of federal regulatory costs by Georgia State University found that it would cost $2.3 billion over a seven-year period for DOL to effectively take over the responsibility for regulation of AHPs. It does

not appear that your budget includes any funding to regulate and oversee AHPs—Does it?

Answer. DOL's current budget does not include funding for AHP certification or enforcement because the legislation has not become law. If the legislation is enacted, we will dedicate the resources necessary to implement it effectively and administer AHPs successfully. As the legislation proceeds through Congress, the Department will work within the Administration to determine the appropriate resources necessary, depending upon the legislative requirements. The costs would depend on many factors, including the number of AHPs that are created, and how many are uninsured. The creation of AHPs may lower our costs in other areas, such as our activities related to Multiple Employer Welfare Arrangements (MEWAs).

Question. How would you regulate AHPs and how much would it cost?

Answer. Under the current legislative proposal, DOL would be responsible for certifying AHPs, and would have ongoing oversight and enforcement authority. For AHP that purchase policies from insurance companies, state insurance regulators would enforce solvency and consumer protection provisions. For self-insured AHPs, DOL would be responsible for overseeing solvency and the consumer protection provisions included in the bill, as well as ERISA's general requirements. Regarding cost, as the legislation authorizing AHPs has not been enacted, DOL cannot speculate on associated costs.

QUESTION SUBMITTED BY SENATOR PATTY MURRAY

COAL INDUSTRY GRANT TO CHINA

Question. Why has $6.4 million been awarded to promote the coal industry in China? What are the details on this grant?

Answer. In the fall of 2002, the department awarded two grants to support activities in China—a $4.1 million grant supports programs that promote the labor rule of law, and a $2.3 million grant provides technical assistance in the enforcement of China's health and safety laws at coal mines. Neither of the two grants was to promote the coal industry in China.

Both grants were awarded through an open and competitive process. The labor rule of law grant was awarded to a consortium formed by Worldwide Strategies, Inc., the Asia Foundation, and the National Committee on U.S.-China Relations. The mine safety and health grant was awarded to the National Safety Council, headquartered in Illinois.

CONCLUSION OF HEARINGS

Senator SPECTER. Thank you all very much for being here. That concludes our hearings.

[Whereupon, at 10:49 a.m., Wednesday, April 9, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2004

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

NONDEPARTMENTAL WITNESSES

[CLERK'S NOTE.—The subcommittee was unable to hold hearings on nondepartmental witnesses. The statements and letters of those submitting written testimony are as follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT OF THE BLUE CROSS AND BLUE SHIELD ASSOCIATION

The Blue Cross and Blue Shield Association (BCBSA), which represents 42 independent, locally operated Blue Cross and Blue Shield Plans throughout the nation, is pleased to submit written testimony to the subcommittee on fiscal year 2004 funding for Medicare contractors.

Blue Cross and Blue Shield Plans play a leading role in administering the Medicare program. Many Plans contract with the federal government to run much of the daily work of paying Medicare claims accurately and timely. Blue Cross and Blue Shield Plans serve as Part A Fiscal Intermediaries (FIs) and/or Part B carriers and collectively process most Medicare claims.

This testimony focuses on three areas:

Background, including a description of Medicare contractor functions;

Current financial challenges facing Medicare contractors; and

BCBSA recommendations for Medicare contractor fiscal year 2004 funding.

BACKGROUND

Blue Cross and Blue Shield Medicare contractors are proud of their role as Medicare administrators. While workloads have soared, operating costs—on a unit cost basis—have declined about two-thirds from 1975 to 2003. In fact, contractors' administrative costs represent less than 1 percent of total Medicare benefits.

Medicare contractors have four major areas of responsibility:

Paying Claims.—Medicare contractors process all the bills for the traditional Medicare fee-for-service program. In fiscal year 2004, it is estimated that contractors will process over one billion claims, more than 3.8 million every working day.

Providing Beneficiary and Provider Customer Services.—Contractors are the main points of routine contact with Medicare for both beneficiaries and providers. Contractors educate beneficiaries and providers about Medicare and respond to over 40 million inquiries annually.

Handling Hearings and Appeals.—Beneficiaries and providers are entitled by law to appeal the initial payment determination made by carriers and FIs. These contractors handle nearly 8 million annual hearings and appeals.

Special Initiatives to Fight Medicare Fraud, Waste, and Abuse.—All contractors have separate fraud and abuse departments dedicated to assuring that Medicare payments are made properly. Few government expenditures produce the documented, tangible savings of taxpayers' dollars generated by Medicare anti-fraud and

abuse activities. For every $1 spent fighting fraud and abuse, Medicare contractors save the government $14.

CURRENT FINANCIAL CHALLENGES

Of utmost importance to attaining outstanding performance is an adequate budget. However, Medicare contractors have been severely underfunded since the early 1990's. Reductions in funding concurrent with increases in workload have seriously eroded contractors' ability to fight fraud and abuse and ensure the accuracy and appropriateness of Medicare payments. Between 1989 and 2002, the number of Medicare claims climbed over 70 percent to nearly 1 billion, while payment review resources grew less than 11 percent. As a result, the amount allocated to contractors to review claims shrank. Because of the significant cost of reviewing claims, this decline in funding resulted in CMS directing contractors to reduce the percentage of claims that were scrutinized and investigated. Similarly, the percentage of cost reports audited declined—between 1991 and 1996, the chances that any institutional provider's cost report would be reviewed in detail fell from about 1 in 6 to about 1 in 13.

The Medicare Integrity Program (MIP) created by Congress in 1996 as part of the Health Insurance Portability and Accountability Act (HIPAA) provided a permanent, stable funding authority for the portion of the Medicare contractor budget that is explicitly designated as fraud and abuse detection activities. MIP funding was set at $500 million in 1998 and rose to $720 million in fiscal year 2003. However, the permanent authorization is now capped at $720 million despite continuing increases in claims volume (11 percent increase in claims is projected in fiscal year 2004).

BCBSA supports the authorized funding mechanism for MIP and urges Congress to extend funding increases beyond fiscal year 2003 so that Medicare contractors can continue important activities to reduce the amount of fraud, waste, and abuse in the Medicare program and ensure accuracy of Medicare payments.

Contractors' enhanced anti-fraud and abuse efforts due to MIP funding contributed to the significant decline in improper claims and deficient documentation submitted by providers. The OIG audit of fiscal year 2002 claims estimated that improper Medicare payments had dropped to $13.3 billion, or about 6.3 percent of the $217.7 billion in Medicare payments. The fiscal year 2002 improper payment rate is the lowest to date and less than half of the 13.8 percent reported in fiscal year 1996.

But, the creation of MIP did not solve the budget problems for the remainder of the contractor budget. The largest portion of the contractor budget—Medicare operations—continues to face severe funding pressures. Medicare operations activities include claims processing, beneficiary and provider education and communications, hearings and appeals of claims initially denied, and systems maintenance and security.

CMS and its Medicare contractors have been severely underfunded for years. The problem has been more acute since passage of HIPAA and subsequent legislation placing additional responsibilities with insufficient resources to perform these new duties. For example, between 1992–2002 Medicare benefits outlays increased 97 percent; claims volume increased 50 percent; yet Medicare operations funding increased a mere 26 percent. Contractors staffing only increased by 6 percent during this time even though many new responsibilities were added and claims volume continued to rise. Clearly funding has not kept pace with additional work.

Whenever possible, contractors respond to reduced funding by achieving significant efficiencies in claims processing, but it has not been enough to keep pace with rising Medicare claims volume and diminishing funding levels. Earlier this year in the absence of appropriated funding contractors were instructed to reduce provider and beneficiary service and offer minimum outreach activities. Since paying claims is a top priority, funds were shifted from other important activities. For example discretionary outreach activities such as mailings to beneficiaries and onsite workshops about benefits and availability of services were curtailed. Provider call quality monitoring activities and in-person training services were reduced. Funding levels also are entirely inadequate to conduct the necessary provider outreach to ensure providers are compliant with the HIPAA electronic transactions and code sets by October 16, 2003.

Inadequate budgets for Medicare operations also impact Medicare's fight against fraud and abuse. While many think of Medicare operations activities as simply paying claims, these activities are Medicare's first line of defense against fraud and abuse and are critically linked to MIP activities. As an example, many of the front-end computer edits (e.g., preventing duplicate payments and detecting inaccurately coded claims or claims requiring additional screening) are funded through Medicare

operations. Inadequate funding impacts different functions at different times, but always disrupts the integration of all the functional components needed to "get things right the first time." It thus results in inefficiency and higher costs.

BCBSA FISCAL YEAR 2004 FUNDING RECOMMENDATIONS FOR MEDICARE CONTRACTORS

BCBSA is pleased that many Members of this subcommittee recognize the need for adequate administrative resources at CMS. We are concerned the Administration's fiscal year 2004 budget does not appropriately reflect the expected costs to cover Medicare workloads and it relies on a proposal for $201 million in new user fees from providers. BCBSA urges Congress to take the following steps to allow Medicare Contractors to meet increased workloads as well as beneficiary and provider needs:

Increase Medicare Contractor Medicare Operations Funding to $1,835 Million for Fiscal Year 2004

Medicare contractors continue to face significant increases in Medicare claims volume. Further reductions in administrative costs, as proposed in the President's budget, would seriously jeopardize contractors' ability to administer Medicare. BCBSA recommends:

Provider Education and Training (PET) Funding be Restored

The President's budget would eviscerate funding for PET from $41.5 million in 2003 to $6.5 million requested for 2004—an 85 percent cut. CMS indicates $30 million will be provided for PET through the MIP program. However this transfer would mean that even fewer claims are reviewed, jeopardizing efforts to safeguard the trust fund. With CMS issuing 172 Medicare program changes in the first quarter of fiscal year 2003, it is critical that contractors have resources to educate providers on constant changes. Further, based on current costs, BCBSA estimates the total annual cost to educate and train providers for fiscal year 2003 will approximate $74 million. If CMS is to meet its goal of reducing the error rate—currently at 6.3 percent—to 4.8 percent in fiscal year 2004, $30 million additional funding is necessary.

Claims Processing Funding Must be Maintained to Handle HIPAA Implementation

The President's budget would decrease claims processing costs by $0.02 per claim under the assumption that HIPAA electronic transactions, effective October 2003, will lower costs. Contractor data show HIPAA is likely to cost more, not less, particularly since many providers are not likely to be compliant by the deadline. This will likely result in an increase in more costly paper claims submission and could require contractors to maintain parallel systems. Further, the HIPAA transactions rule is unlikely to result in contractor savings as current Medicare electronic claims submission rates are already extremely high—98 percent of Medicare Part A and 84 percent of Medicare Part B. CMS currently provides contractors with higher unit costs for processing claims due to increased claims volume. There is every indication that claims volume will continue to exceed estimates, putting additional pressure on the cost of processing claims. Therefore, the current unit costs for processing Medicare claims must be maintained, requiring an additional $22 million.

Systems Security Funding Must be Enhanced

The President's budget would substantially reduce funding for critical activities such as systems maintenance, security and CMS operations. Adequate funding is imperative to ensure software is updated, new applications are tested, systems are secure, provider toll-free lines are staffed, and provider bills are appropriately paid. BCBSA recommends an additional $6 million for these important activities.

Increase Medicare Integrity Program (MIP) Funding to $740 Million

MIP anti-fraud and abuse funding must be increased by a minimum of $20 million to keep pace with rising workloads, which are projected to increase 11 percent in 2004. The President's budget does not provide any increased funding for MIP and in fact diverts $30 million even though HHS data shows $14:1 return on the investment. Inadequate funding will curtail important activities such as medical review and Medicare secondary payer activities—both of which significantly contribute to program savings and recoveries.

As the fiscal year 2004 Labor/HHS/Education appropriations process begins, we urge Congress to fund Medicare contractor as follows:

MEDICARE CONTRACTOR BUDGET

[In millions of dollars]

	Fiscal year 2003	Administration fiscal year 2004 recommendation	BCBSA fiscal year 2004 recommendation
Medicare Operations	1,748.0	1,777.0	1,835.0
Medicare Contractor Ongoing Activities	1,128.0	1,184.0	1,235.0 (+52)
Systems Maintenance	85.0	72.1	78.1 (+6)
CMS Operations	103.0	82.6	82.6
Enterprise Activities	59.0	53.0	53.0
Legislative Mandates	343.0	354.0	354.0
Program Improvements	19.0	17.3	17.3
Information Technology Infrastructure Plan	11.0	14.0	14.0
Total, Medicare Operations	1,748.0	1,777.0	1,835.0 (+58)
Medicare Integrity Program	720.0	720.0	740.0
Total Contractor Budget	2,468.0	2,497.0	2,575.0

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF FAMILY PHYSICIANS

The 94,300 member American Academy of Family Physician submits the following statement for the record on three issues of critical importance to family physicians in the United States: (1) funding for family medicine training in Section 747 of the Public Health Service Act; (2) funding for the Agency for Healthcare Research and Quality (AHRQ); and (3) funding for rural health programs. We deeply appreciate the level of funding provided for the Title VII Health Professions Programs for fiscal year 2003 during a challenging appropriations process.

FAMILY MEDICINE TRAINING PROGRAMS

Recommendation

The Academy continues to support appropriations of $169 million for Section 747 of Title VII of the Public Health Service Act for fiscal year 2004.—Section 747 authorizes the Primary Care and Dentistry cluster, which includes support for family medicine, general internal medicine and general pediatrics, physician assistants and general and pediatric dentistry. This figure includes $96 million for family medicine programs and is the result of consultation between the groups receiving funding under this cluster.

President's Budget Request for Fiscal Year 2004 Zeros Out Primary Care Funding

As you know, the President's budget once again zeroes out funding for the Primary Care Medicine and Dentistry cluster. In addition, the Administration proposal includes only $11 million for all Title VII Health Professions programs, which is the same request made last year. Fiscal year 2003 spending levels for Title VII were $295 million. Funding is directed only to "increasing diversity in the health professions and nursing workforce." The proposal continues, "The fiscal year 2004 budget continues the policy of not funding more general training efforts—primary care, interdisciplinary community projects, training for diversity and public health."

What Does Title VII Do?

Section 747 is the only program at the federal level that supports family medicine training programs at both the undergraduate and graduate level. It is designed to increase both the number of primary care physicians and the number of individuals who will provide health care to the underserved. The program has succeeded in achieving its goals and Congress should support it at higher funding levels.

Title VII Meets Its Goals: Grants Increase the Number of Primary Care Physicians

Due to Section 747 funding, thousands of physicians are making career choices to go into primary care and family medicine and to serve millions of patients.

A study by the Robert Graham Center for Policy Studies showed that medical schools that received Section 747 family medicine funds produced more medical students who practiced ultimately:

—in family medicine or primary care (family physicians, general practitioners, general internists or general pediatricians);
—in a rural area; or
—in a whole county Primary Care Health Professions Shortage Area (those counties with inadequate numbers of family physicians, general pediatricians, general internists or obstetrician/gynecologists).

Sustained funding during the years of medical school training had more positive impact than intermittent funding.

Loss of Grant Funding Would Hurt the Underserved

Without family physicians, counties around the United States would not receive essential primary care services.—Another study by the Robert Graham Center showed that the United States relies on family physicians more than any other physician specialty. Specifically, the study looked at counties designated as Primary Care Health Professions Shortage Areas (HPSAs).

Of the 3,142 counties in the United States, 1,189 (63 percent) are designated full or partial county HPSAs, meaning that the desired ratio of one primary care physician to 3,500 people is not met. If family physicians are removed or choose to remove themselves from the system, the large majority of U.S. counties would become full or partial county HPSAs.

In addition, an article in The Journal of Rural Health found that Title VII funding is key to ending HPSAs. According to the study, without this funding, not only would HPSAs not be eliminated, but the number of shortage areas would continue to grow. In addition, the article states that Title VII funding has cut to 15 years the time needed to eliminate all HPSAs. Doubling the funding for these programs would decrease the time for HPSA elimination to as little as 6 years (Robert M. Politzer, ScD, et al., Winter, 1999). It is clear that underserved populations, particularly in rural areas, depend on the care that family physicians provide.

Section 747 Advisory Committee Recommends Higher Funding

In 1998, Congress established an Advisory Committee to review and make recommendations on Section 747. The Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) recently released their recommendations to Congress and the Secretary of the Department of Health and Human Services. The first of six recommendations urges greatly expanding federal support for Section 747 to $198 million. The Committee notes the growing need for primary care providers, as well as the success of Title VII funded programs

Proposed OMB Performance Measures Need to Be Redefined

The performance measures proposed recently by the Office of Management and Budget to gauge effectiveness are neither measurable nor appropriate. Consequently, assessments based on these conclusions are highly flawed.

For example, the target set for the proportion of underrepresented minorities (URMs) and disadvantaged students in health professions funded programs is set at 40 percent for 2004. This is the target although only 12.5 percent of current medical school graduates are URMs, and data on disadvantaged backgrounds is not routinely, or even accurately, collected. The concept of disadvantaged background varies based on income related to family size, or is based on a vague, non-quantifiable notion of persons growing up in environments that do not prepare them to enter health professions schools.

For all of the health professions, minority representation has risen from 8.3 percent in 1985 to 11.7 percent in 2000. Given this data, it is simply unrealistic to expect a health professions program to increase its minority representation in one year to 40 percent.

Future Funding Priorities

ACTPCMD's report to Congress lays out priorities for training primary care providers. If additional funds are made available, Title VII dollars could enhance current training, allowing the program to be even more effective at providing:

—high-quality health care for underserved populations
—culturally competent care
—continued demonstration authority to address emerging health initiatives
—additional interdisciplinary learning opportunities
—better quality of health care, eliminating health disparities, and improving patient safety

Primary Care Training Programs React Quickly to Emerging Health Challenges

Title VII dollars have created an infrastructure that allows educational programs to respond to contemporary health care issues. Specifically, the ACTPCMD report states that:

"Investment in education to provide primary care has effects that touch the largest number of people in the country. No other group of health care providers can exert such a broad influence on the kind and quality of health care in the United States. Primary care training programs are ideally positioned to react quickly to meet ever-changing health care needs and issues, whether they are related to HIV/AIDS, growing numbers of elderly with chronic illnesses, implications of the modern genetics revolution, the threat of bioterrorism, or other issues that will continue to emerge and demand rapid educational intervention. Thus, this infrastructure is uniquely able to play a pivotal role in bringing emerging issues in health care to the population at large."

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Recommendation

We recommend appropriations of $390 million for the Agency for Healthcare, Research and Quality (AHRQ) in fiscal year 2004.—AHRQ conducts primary care and health services research geared to physician practices, health plans and policymakers that helps the American population as a whole.

What Does AHRQ Do?

AHRQ has the following three goals:

—Improve physician practice and Americans' health outcomes;

—Improve the quality of health care (e.g., patient safety);

—Improve the health care system (e.g., increase access and reduce costs).

In brief, AHRQ "helps to improve the health and health care of the American people . . ."——(AHRQ report, March, 2001).

President's Budget Request for Fiscal Year 2004 Cuts AHRQ Funding

The Agency for Healthcare Research and Quality receives only $279 million in the President's proposal; the current funding level is $299 million. Of this figure, $84 million is slated for patient safety efforts, which includes $50 million for activities related to information technology investments defined as computerized physician order entry, computer monitoring for potential adverse drug events and computerized patient records, among others. In addition, $10 million is targeted to "promoting and accelerating the development, adoption and diffusion of information technology in health care."

How Does AHRQ Meet Its Goals?

AHRQ translates basic science research findings like those of the National Institutes of Health into information that doctors can use every day in their practice. Another key function of the agency is to support research on the conditions that affect most Americans.

AHRQ Translates Research into Everyday Practice

Congress has provided billions of dollars to the National Institutes of Health, which has resulted in important insights in preventing and curing major diseases. AHRQ takes this basic science and produces information that physicians can use every day in their practices. AHRQ also distributes this information throughout the health care system. In short, AHRQ is the link between research and the patient care that Americans receive.

For example, research shows that beta blockers reduce mortality. AHRQ supported research to help physicians determine which patients with heart attacks would benefit from this medication.

AHRQ Supports Research on Conditions Affecting Most Americans

Most typical Americans get their medical care in doctors' offices and clinics. However, most medical research comes from the study of extremely ill patients in hospitals. AHRQ studies and supports research on the types of illness that trouble most people. In brief, AHRQ looks at the problems that bring people to their doctors—not the problems that send them to the hospital.

For example, AHRQ supported research that found older, cheaper antidepressant drugs are as effective as new antidepressant medications in treating depression, a condition that affects millions of Americans.

Institute of Medicine Recommends $1 Billion for AHRQ

The Institute of Medicine's report, Crossing the Quality Chasm: A New Health System for the 21st Century (2001) recommended $1 billion for AHRQ to "develop strategies, goals, and actions plans for achieving substantial improvements in quality in the next 5 years . . ." The report looked at redesigning health care delivery in the United States. AHRQ is a linchpin in retooling the American health care system.

RURAL HEALTH PROGRAMS

Finally, the Academy supports continued funding for several rural health programs. In particular, we support the programs of the Federal Office of Rural Health Policy; Area Health Education Centers, two programs that are equally important to health care in rural areas and in our inner cities; the Community and Migrant Health Center Program; and the National Health Services Corps. State rural health offices, funded through the National Health Services Corps budget, help states implement these programs so that rural residents benefit as much as urban dwellers. Continued funding for these rural programs is vital if we wish to provide adequate health care services to America's rural citizens.

PREPARED STATEMENT OF THE DIGESTIVE DISEASE NATIONAL COALITION

SUMMARY OF FISCAL YEAR 2004 RECOMMENDATIONS

—Provide increased funding for the National Institutes of Health (NIH) at 10 percent for fiscal year 2004. Increase funding for the National Cancer Institute (NCI), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Allergy and Infectious Diseases by 10 percent for fiscal year 2004.
—Continue focus on digestive disease research and education at NIH, including the areas of Inflammatory Bowel Disease (IBD), Hepatitis and other liver diseases, Irritable Bowel Syndrome (IBS), Colorectal Cancer, Endoscopic Research, Pancreatic Cancer, Celiac Disease, and Hemochromatosis.
—$25 million for the Centers for Disease Control and Prevention's (CDC) National Colorectal Cancer Awareness Program.

Chairman Specter, thank you for the opportunity to again submit testimony to the Subcommittee. Founded in 1978, the Digestive Disease National Coalition (DDNC) is a voluntary health organization comprised of 25 professional societies and patient organizations concerned with the many diseases of the digestive tract. The Coalition has as its goal a desire to improve the health and the quality of life of the millions of Americans suffering from both acute and chronic digestive diseases.

The DDNC promotes a strong federal investment in digestive disease research, patient care, disease prevention, and public awareness. The DDNC is a broad coalition of groups representing disorders such as Inflammatory Bowel Disease (IBD), Hepatitis and other liver diseases, Irritable Bowel Syndrome (IBS), Pancreatic Cancer, Ulcers, Pediatric and Adult Gastroesophageal Reflux Disease, Colorectal Cancer, Celiac Disease, and Hemochromatosis.

Mr. Chairman, the social and economic impact of digestive disease is enormous and difficult to grasp. Digestive disorders afflict approximately 65 million Americans. This results in 50 million visits to physicians, over 10 million hospitalizations, collectively 230 million days of restricted activity. The total cost associated with digestive diseases has been conservatively estimated at $60 billion a year.

The DDNC would like to thank the subcommittee for its past support of digestive disease research and prevention programs at the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). With respect to the coming fiscal year the DDNC is recommending an increase of 10 percent to $29.8 billion for the National Institutes of Health (NIH) and all of its Institutes. Specifically the DDNC recommends that the National Cancer Institute (NCI), the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), and the National Institute of Allergy and Infectious Diseases (NIAID be given $5.08 billion, $1.79 billion, and $4.1 billion respectively. We at the DDNC respectfully request that any increase for NIH does not come at the expense of other Public Health Service agencies.

With the historic doubling of the budget for NIH completed and the challenging budgetary constraints the Subcommittee currently operates under, the DDNC would like to highlight the research being accomplished by NIDDK which warrants the increase for NIH.

INFLAMMATORY BOWEL DISEASE

In the United States today about 1 million people suffer from Crohn's disease and ulcerative colitis, collectively known as Inflammatory Bowel Disease (IBD). These are serious diseases that affect the gastrointestinal tract causing bleeding, diarrhea, abdominal pain, and fever. Complications arising from IBD can include anemia, ulcers of the skin, eye disease, colon cancer, liver disease, arthritis, and osteoporosis. Crohn's disease and ulcerative colitis are not usually fatal but can be devastating. The cause of IBD is still unknown, but research has led to great breakthroughs in therapy.

In recent years researchers have made significant progress in the fight against IBD. In 1998, the FDA approved the first drug ever specifically to fight Crohn's disease, a remarkable milestone. The DDNC encourages the subcommittee to continue its support of IBD research at NIDDK and NIAID at a level commensurate with the overall increase for each institute. The DDNC would like to applaud the NIDDK for its strong commitment to IBD research through the Inflammatory Bowel Disease Genetics Research Consortium. The DDNC urges the Consortium will continue its work in IBD research. The DDNC would also commend NIDDK for organizing and hosting the upcoming meeting entitled "Research on Inflammatory Bowel Disease," later this month.

Given the recent advancements in treatment for these diseases and the increased risk that IBD patients have for developing colorectal cancer, the DDNC strongly believes that generating improved epidemiological information on the IBD population is essential if we are to provide patients with the best possible care. Therefore the DDNC and its member organization the Crohn's and Colitis Foundation of America encourage the CDC to initiate a nationwide IBD surveillance and epidemiological program in fiscal year 2004.

HEPATITIS C: A LOOMING THREAT TO HEALTH

It is estimated that there are over 4 million Americans who have been infected with Hepatitis C of which over 2.7 million remain chronically infected. About 10,000 die each year and the Centers for Disease Control and Prevention (CDC) estimates that the death rate will more than triple by 2010 unless there is additional research, education, and more effective treatments and public health interventions. Hepatitis C infection is the largest single cause for liver transplantation and one of the principal causes of liver cancer and cirrhosis. There is currently no vaccine for hepatitis C, and treatment has limited success, making the infection among the most costly diseases in terms of health care costs, lost wages, and reduced productivity. Patients who are older at the time of infection, those who continually ingest alcohol, and those co-infected with HIV demonstrate accelerated progression to more advanced liver disease.

The DDNC applauds all the work NIH and CDC have accomplished over the past year in the areas of hepatitis and liver disease. An example of this commitment has been the convening of the second National Institutes of Health Management of Hepatitis C Consensus Development Conference, which occurred in June 2002. The Conference made 17 specific and high priority research recommendations that need to be pursued to develop better treatments and a cure for hepatitis. The DDNC urges that these recommendations be funded in fiscal year 2004. The DDNC also commends NIDDK for the establishment of the Biliary Atresia Research Consortium and the Adult-to-Adult Living Donor Liver Transplant Cohort Study. The convening of conferences on Hepatitis C and Renal Disease and Hepatitis C in Prisons, plus the New Direction for Therapy of Primary Biliary Cirrhosis are just some more positive examples of the work NIDDK has undertaken to combat hepatitis and liver disease. The DDNC urges NIDDK to continue support research in this area.

The DDNC supports $30 million for the CDC's Hepatitis Prevention and Control activities. The hepatitis division at CDC supports the hepatitis C prevention strategy and other cooperative nationwide activities aimed at prevention and awareness of hepatitis A, B, and C. The DDNC also urges the CDC's leadership and support for the National Viral Hepatitis Roundtable to establish a comprehensive approach among all stakeholders for viral hepatitis prevention, education, strategic coordination, and advocacy.

COLORECTAL CANCER PREVENTION

Colorectal cancer is the third most commonly diagnosed cancer for both men and woman in the United States and the second leading cause of cancer-related deaths. Colorectal cancer affects men and women equally. Although colorectal cancer is preventable and curable when polyps are detected early, a General Accounting Office

report issued in March 2000 documented that less than 10 percent of Medicare beneficiaries have been screened for colorectal cancer. This report revealed a tremendous need to inform the public about the availability of screening and educate health care providers about colorectal cancer screening guidelines. In 2003, the New York City Department of Health has recommended colonoscopy for everyone over age 50 to prevent colorectal cancer.

The DDNC recommends a funding level of $25 million for the CDC's Colorectal Cancer Screening and Prevention Program. This important program supports enhanced colorectal screening and public awareness activities throughout the United States. The DDNC also supports the continued development of the CDC-supported National Colorectal Cancer Roundtable, which provides a forum among organizations concerned with colorectal cancer to develop and implement consistent prevention, screening, and awareness strategies.

PANCREATIC CANCER

In 2002, an estimated 28,300 people in the United States were found to have pancreatic cancer and approximately 28,200 died from the disease. Pancreatic cancer is the fifth leading cause of cancer death in men and women. Only 2 out of 10 patients will live 1 year after the cancer is found and only a very few will survive after 5 years. Although we do not know exactly what causes pancreatic cancer, several risk factors linked to the disease have been identified:

(1) Age: Most people are over 60 years old when the cancer is found;
(2) Sex: Men have pancreatic cancer more often than women;
(3) Race: African Americans are more likely to develop pancreatic cancer than are white or Asian Americans;
(4) Smoking;
(5) Diet: Increased red meats and fats; and
(6) Diabetes.

The National Cancer Institute (NCI) has established a Pancreatic Cancer Progress Review Group charged with developing a detailed research agenda for the disease. The DDNC commends NIDDK for the establishment in 2002 on an initiative entitled: Liver, Pancreas, and Gastrointestinal Cell Genome Anatomy Project. The DDNC hopes this new initiative will call more attention and greater resources to the diseases of the Pancreas. The DDNC encourages the Subcommittee to provide an increase for pancreatic cancer research at a level commensurate with the overall percentage increase for NCI and NIDDK.

IRRITABLE BOWEL SYNDROME (IBS)

IBS is a disorder that affects an estimated 35 million Americans. The medical community has been slow in recognizing IBS as a legitimate disease and the burden of illness associated with it. Patients often see several doctors before they are given an accurate diagnosis. Once a diagnosis of IBS is made, medical treatment is limited because the medical community still does not understand the pathophysiology of the underlying conditions.

Living with IBS is a challenge, patients face a life of learning to manage a chronic illness that is accompanied by pain and unrelenting gastrointestinal symptoms. Trying to learn how to manage the symptoms is not easy. There is a loss of spontaneity when symptoms may intrude at any time. IBS is an unpredictable and fickle disease. A patient can wake up in the morning feeling fine and within a short time encounter abdominal cramping to the point of being doubled over in pain and unable to function.

The unpredictable bowel symptoms may make it next to impossible to leave your home. It is difficult to ease the pain than may repeatedly occur periodically throughout the day. A patient can become reluctant to eat for fear that just eating a meal will trigger symptoms all over again. IBS has a broad and significant impact on a person's quality of life. It strikes individuals from all walks of life and results in a significant toll of human suffering and disability.

While there is much we don't understand about the causes and treatment of IBS, we do know that IBS is a chronic complex of systems affecting as many as one in five adults. In addition;

(1) It is reported more by women than men;
(2) It is the most common gastrointestinal diagnosis among gastroenterology practices in the United States;
(3) It is a leading cause of worker absenteeism in the United States; and
(4) It costs the U.S. Health Care System an estimated $8 billion annually.

Mr. Chairman, much more can still be done to address the needs of the nearly 35 million Americans suffering from irritable bowel syndrome and other functional gastrointestinal disorders.

CELIAC DISEASE

Celiac Disease is a life-long condition in which the body develops an allergy to gluten, a protein found in wheat, barley, and rye, which can result in damage to the small intestine. Celiac disease affects as many as two million Americans. Onset of the disease can occur at any age. The common symptoms of Celiac Disease include fatigue, anemia, chronic diarrhea or constipation, weight loss, and bone pain. The only treatment for celiac disease is strict adherence to a gluten-free diet. Undiagnosed and untreated celiac disease can lead to other disorders such as osteoporosis, infertility, neurological conditions, and in rare cases cancer. Persons with Celiac Disease often have other associated autoimmune disorders as well.

The DDNC along with our Celiac Disease applauds the NIDDK for organizing and hosting the upcoming meeting entitled "Consensus Development Conference on Celiac Disease." The DDNC urges the Subcommittee to recommend more research, medical education, and public awareness around Celiac Disease.

The DDNC understand the challenging budgetary constraints and times we live in that is subcommittee is operating under, yet we hope you will carefully consider the tremendous benefits to be gained by supporting a strong research and education program at NIH and CDC. Millions of Americans are pinning their hopes for a better life, or even life itself, on digestive disease research conducted through the National Institutes of Health.

Mr. Chairman, on behalf of the millions of digestive disease sufferers, we appreciate your consideration of the views of the Digestive Disease National Coalition. We look forward to working with you and your staff.

DIGESTIVE DISEASE NATIONAL COALITION

The Digestive Disease National Coalition was founded 25 years ago. Since its inception, the goals of the coalition have remained the same: to work cooperatively to improve access to and the quality of digestive disease health care in order to promote the best possible medical outcome and quality of life for current and future patients with digestive diseases.

PREPARED STATEMENT OF THE IMMUNE DEFICIENCY FOUNDATION

Mr. Chairman, thank you for the opportunity to testify today on behalf of the Immune Deficiency Foundation (IDF).

IDF is the national non-profit, voluntary health organization dedicated to improving the treatment of primary immune deficiency diseases through research and education. Head-quartered in Towson, Maryland, IDF was founded in 1980 by a group of parents of primary immune deficient children who wanted to focus attention on the needs of primary immune deficient patients, physicians, and researchers.

Primary immune deficiency diseases are inherited disorders in which parts of the body's immune system are missing or do not function properly. The World Health Organization has identified more than 70 different primary immune deficiency diseases. These disorders affect an estimated 50,000 Americans, regardless of race, age, or gender.

Fortunately, most primary immune deficient patients are able to maintain their health through regular infusions of intravenous immunoglobulin (IGIV). IGIV is a pooled plasma derivative that bolsters the patient's immune system. IGIV is administered intravenously every three weeks for the lifetime of the patient. However, if primary immune deficiency diseases are not properly diagnosed and treated, they can lead to serious illness and early death.

I am here today to speak as a patient, but I am also a physician. My case is quite representative of a typical immune deficient patient. I was diagnosed with Common Variable Immuno-deficiency 10 years ago, following years of repeated infections, which were unresponsive to antibiotics, and undiagnosed by numerous physicians who were colleagues of mine. This led to numerous unsuccessful surgeries resulting in permanent lung and sinus damage. Prior to my diagnosis, a day was considered successful if I had enough energy to get out of bed. Following appropriate diagnosis and treatment with IGIV, I have been able to return to my medical practice and have a new lease on life.

In my testimony today, I would like to highlight the following issues of importance to the primary immune deficiency community:

—Primary immune deficiency research at the National Institutes of Health, including the National Institute of Allergy and Infectious Diseases' Primary Immunodeficiency Disease Research Consortium.
—Protection for primary immune deficiency patients as part of the Centers for Disease Control and Prevention's smallpox vaccination campaign.

PRIMARY IMMUNE DEFICIENCY RESEARCH AT THE NATIONAL INSTITUTES OF HEALTH

Mr. Chairman, I would like to take this opportunity to thank the subcommittee for its longstanding support of biomedical research at the National Institutes of Health. IDF applauds your leadership in finalizing the five-year effort to double the NIH budget in fiscal year 2003. For fiscal year 2004, we encourage the subcommittee to provide a 10 percent increase to NIH in fiscal year 2004. Moreover, we urge the subcommittee to continue its support of primary immune deficiency research at the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Child Health and Human Development (NICHD), and the National Cancer Institute (NCI).

NIAID Primary Immune Deficiency Disease Research Consortium

Mr. Chairman, NIAID is currently in the process of establishing a Primary Immune Deficiency Disease Research Consortium. IDF welcomes this exciting new initiative, which will establish a cooperative group of investigators to address clinical and pre-clinical research questions, including the development of new treatments such as gene therapy. The Consortium will utilize the current registry of primary immune deficiency patients, which IDF and NIAID currently administer jointly. These registries provide a comprehensive clinical picture of each primary immune deficiency disorder, including estimates of disease prevalence, clinical course, and complications.

Another important element of the Consortium is a repository for biomedical specimens. IDF encourages the subcommittee to support this critical research component. The Foundation looks forward to working closely with NIAID in the development and management of the Consortium. We believe that IDF is uniquely positioned to serve as NIAID's primary partner on this important new initiative. We encourage the subcommittee to support the Primary Immune Deficiency Disease Research Consortium at a level of $12.8 million in fiscal year 2004.

PROTECTION FOR PRIMARY IMMUNE DEFICIENT PATIENTS AS PART OF CDC'S SMALLPOX VACCINATION PROGRAM

Mr. Chairman, as you know, our nation has been involved in a difficult debate over the issue of vaccinating Americans against smallpox. The Immune Deficiency Foundation supports the Administration's goal of protecting Americans, specifically our first responders, from the threat of this terrible disease. However, we believe it is critical that the federal government take all prudent steps to protect vulnerable populations from the potential ill effects of exposure to the smallpox vaccine.

Because of their compromised immune systems, primary immune deficient patients should not be vaccinated against smallpox. Unfortunately, the potential exists for primary immune deficiency patients to contract life-threatening complications from just being exposed to an individual who has been vaccinated. Consequently, IDF has been working closely with CDC to ensure that the agency's educational materials related to the smallpox vaccination campaign include appropriate references to the unique concerns of the primary immune deficiency community. We are pleased that CDC has incorporated our proposed references to primary immune deficiency patients in their printed materials and on their smallpox prevention website.

Mr. Chairman, thank you for the opportunity to present the views of the Immune Deficiency Foundation. We look forward to continuing to work with you on these important issues.

PREPARED STATEMENT OF THE NATIONAL AREA HEALTH EDUCATION CENTERS ORGANIZATION

SUMMARY OF FISCAL YEAR 2004 RECOMMENDATIONS

1. Increase funding for the health professions and nursing education programs under Title VII and Title VIII of the Public Health Service Act to at least $550 million for fiscal year 2004.
2. Increase funding for Area Health Education Centers (AHECs) to $40 million.
3. Increase funding for Health Education Training Centers (HETCs) to $10 million.

Mr. Chairman, and members of the subcommittee, I am pleased to present testimony on behalf of the National AHEC Organization.

I am director of the Ohio Statewide AHEC Program, director of the Medical College of Ohio AHEC program, and a member of the National AHEC Organization. NAO is the professional organization representing the Area Health Education Centers (AHECs) and Health Education Training Centers (HETCs). Together, we seek to enhance access to quality health care, particularly primary care and preventative care, by improving the supply and distribution of health care professionals through community-academic partnerships

PERSISTENT WORKFORCE SHORTAGES

Mr. Chairman, contrary to what may be commonly understood, persistent and severe shortages exist in a number of health professions. Chronic shortages exist for all health professions in many of our nation's underserved communities, and substantial shortages exist in all communities for some professions such as nursing, pharmacy, and certain allied health fields. While the supply of physicians in the non-primary care specialties may well be adequate, supply and distribution problems for primary care physicians, nurses, and many allied health professionals are undermining access and quality in many of our nation's communities.

Historically, the supply of and demand for health care professionals has waxed and waned in a manner that produced cycles of shortage and excess. However, it is reasonable to believe that the current shortages are of a different and more persistent nature. First, the breadth and depth of shortages are greater than at any time in the past. More disciplines are in short supply, more sites of care (hospitals, nursing homes, home care agencies, and clinics) are experiencing shortages, and the duration of vacancies is longer. Second, the demand for health care services is steadily and inexorably increasing due to the aging population and the advances in medical technology. Third, the health care provider population is aging itself. Fourth, the resources with which the health care industry might respond to shortages are inadequate to the challenges. Due to the squeeze of managed care, provider institutions are unable to increase salaries, and due to cuts in government funding, educational institutions are unable to expand class sizes. Finally, the career opportunities available to women, who dominate the health care professions, have expanded greatly.

Health care workforce shortages are occurring in a context of an increasingly aged population with greater needs for health care services. In addition, health technology steadily produces advances that require a higher level of training and sophistication on the part of health care providers. These trends are occurring at time when the number and the level of academic preparedness of students entering the health professions are decreasing.

In addition, minority and disadvantaged populations are egregiously under represented in the health professions. Given the demographic trends in the United States, minority populations constitute a major untapped source of future health care professionals.

WHAT AHECS DO

Mr. Chairman, the AHEC/HETC network is the federal government's most flexible and efficient mechanism for addressing a wide and evolving variety of health care issues on a local level. Through AHECs and HETCs, national initiatives can be targeted to the areas of greatest need and molded to the particular issues confronting individual communities. Whether the issue is the nursing shortage, bioterrorism preparedness, access for the uninsured, or recruiting under-represented minority students into the health professions, AHECs and HETCs, where they exist, can assemble the appropriate local collaboration and apply federal, state, and local resources in a precise and cost-effective manner.

Since our inception almost thirty years ago, AHECs have partnered with local, state, and federal initiatives and educational institutions in providing clinical training opportunities to health professions and nursing students in rural and underserved communities. We bring the resources of academic health centers to bear in addressing the health care needs of these communities. Currently, there are 46 AHEC programs and 180 centers located in 43 states and the District of Columbia. AHEC programs are based at schools of medicine, which are the federal AHEC grant recipients, and are implemented through the regional offices (centers), each of which serves a defined geographic area.

AHEC programs perform four basic functions:

1. They develop and support the community based training of health professions students, particularly in underserved rural and urban areas. Exposing health pro-

fessions students to underserved communities increases the likelihood that they will return to these communities to practice.

Last year (2001–2002 academic year), Ohio's AHECs supported the clinical education of 578 nursing students and 1353 medical students and residents at community-based rural and underserved sites. Ohio AHECs have developed a network of over 800 physicians who volunteer their time to teach the next generation of health professionals. Through the AHEC in their region (the Canton Area Regional Health Education Network), nutrition students from Kent State University-Stark Campus are placed in senior centers to provide nutritional assessments of older adults at risk of malnutrition and chronic disease. The students benefit from clinical experience and the seniors obtain a valuable but otherwise unavailable service.

2. They provide continuing education and other services that improve the quality of community-based health care. Improving the quality of care also enhances the retention of providers in underserved communities, particularly community health centers.

For example, last year Ohio AHECs provided more than 516 continuing education programs, which were attended by 10,972 practicing professionals. These providers did not have to leave their communities or arrange practice coverage to attend these programs, because the education programs were brought to them in their local communities. In this way Ohio AHECs support the viability and, often, the continued, independent existence of small community hospitals. The Sandusky AHEC sponsors monthly clinical cancer conferences at nine small hospitals, which routinely attract the entire medical staff.

3. They recruit under-represented minority students into the health professions through a wide variety of programs targeted at elementary through high schools. Minority students are grossly under-represented in the health professions and are more likely to practice in underserved communities.

Ohio AHECs provide schoolchildren with classroom education on health careers, school counselors with updates on the latest opportunities in the health careers, summer science and medicine camps', and health career directories for schools.

Additionally, the AHEC in Tuscarawas, Ohio is now training 16 promatoras to become community health workers to improve the health of Hispanic populations. Currently, health fairs are being planned for this population with local social service agencies. The promatoras will staff each agency table to translate and we hope that the agencies will hire them for future translation assistance. In addition, it is funding three medical students this summer. Each will spend 8 weeks to develop health-screening events, develop a Hispanic health risk assessment, and assist physicians in Hispanic populations to provide medical care and teach cultural competence.

4. They facilitate and support practitioners, facilities, and community based organizations in addressing critical local health issues in a timely and efficient manner.

Ohio has the fourth highest death rate due to diabetes in the country. Incidence of the disease is much higher among the poor, older adults, African Americans, and Hispanics. Nearly 50 percent of Ohioans read at a 5th grade level or lower, greatly reducing the ability for patients to manage their condition well and to understand the information presented to them. That is why the Ohio Statewide AHEC Program developed the "Best Practices and Real Results Conference: Diabetes and Literacy." This conference will assist health care professionals to understand the growing burden of diabetes, and the impact of low literacy.

THE ROLE OF HETCS

The HETC programs were created to address the public health needs of severely underserved populations in border and non-border areas. Currently, HETC programs exist in 12 states and are supported by a combination of federal, state, and local funding, the majority of which comes from non-federal sources.

Because the majority of preventable health problems are due to health behaviors and the environment, HETCs focus on community health education and health provider training programs in areas with severely underserved populations. HETCs target minority groups, disadvantaged communities, and communities with diverse culture and languages.

COLLABORATIVE EFFORTS

Virtually all AHEC and HETC programs are collaborative in nature. They routinely partner with a wide variety of federal, state, and locally funded programs. Examples of these collaborations include health professions schools, primary care residency programs, community health centers, primary care associations, geriatric education centers, the National Health Service Corps, public health departments, health career opportunity programs, school districts, and foundations.

Additionally, AHECs and HETCs often go beyond their core functions to undertake a wide variety of innovative programs that are tailored to specific health issues affecting the communities they serve. Because health issues vary from community to community, the programs of each AHEC and HETC also vary considerably. AHECs and HETCs respond to changing health and health workforce needs in a flexible and timely manner. Examples of current issues for which we are directing our resources are:

1. *The nursing shortage*.—Currently, AHECs and HETCs are working with schools of nursing, state nursing associations, and others to increase the number of qualified applicants to nursing schools, increase minority enrollment in nursing schools, expand the number of community-based nursing training sites, and retrain nurses who wish to re-enter the profession.

Ohio's AHECs are attacking the nursing shortage at multiple levels; from leadership at both local and state level policy and education planning forums to directly providing health career education programs to high school students. The AHEC in Allen County began a RN-to-BSN program several years ago. By providing pre-admission counseling, arranging local and on-line coursework and instructors, and placing in local hospitals computer workstations linked to the Medical College of Ohio library, RNs can remain on the job in the community while obtaining a BSN degree. In the past eight years over 400 nurses have completed the program.

2. *Bioterrorism education*.—Currently, AHECs and HETCs are working with public health departments to educate health and public health professionals on surveillance, reporting, risk communication, treatment, and other responses to the threat of bioterrorism.

Ohio's AHECs have stepped in to provide health professionals with the latest updates on bioterrorism. In rural areas of the state, which often do not have satellite capabilities, AHECs bring in downlinks and sponsor bioterrorism preparedness programs. In 2002 Statewide Ohio AHEC Program received one of 6 federal bioterrorism grants to fund a two component approach to bioterrorism training and education for health professionals in Ohio. The focus of the training us on skills necessary for a wide range of health professionals to be prepared to offer medical assistance in the first moments through 12 to 24 hours after an act of terrorism. This year, the Statewide Ohio AHEC Program began its Basic Anti-Terrorism Emergency Life-Saving Skills (BATELS) program to prepare health care professionals with a basic fund of knowledge concerning intentional incidents within the context of an all hazards disaster management approach. After one session, the Statewide Ohio AHEC has trained 70 health care professionals, most of whom work in community health centers. At the Medical College of Ohio, BATELS is a required course for medical students, and is provided by the school's AHEC program.

3. *The National Health Service Corps (NHSC)*.—AHECs and HETCs undertake a variety of programs related to the placement and support of NHSC scholars and loan repayment recipients.

The Ohio University AHEC has actively supported the NHSC "SEARCH" program by interviewing prospective students, recommending community preceptors, and monitoring placements of 15 students each summer in rural and Appalachian sites.

4. *Expansion of community health centers*.—AHECs and HETCs are collaborating with health professions schools, primary care associations, and community health centers to increase the supply of providers willing and able to work in community health centers. In addition, AHECs/HETCs are working directly with CHC providers to improve the quality of care

The Ohio AHEC program and the Ohio Primary Care Association have worked together to promote and support their complementary missions through co-sponsorship of educational programs and development of clinical sites such as, "Diabetes and Literacy" and "BATELS" for community health centers.

JUSTIFICATION FOR FUNDING RECOMMENDATIONS

Mr. Chairman, I respectfully ask the Subcommittee to support our recommendations to increase funding for the health professions and nursing education programs under Title VII and Title VIII of the Public Health Service Act to at least $550 million. Our recommendations are consistent with those of the Health Professions and Nursing Education Coalition (HPNEC).

The AHEC and HETC programs improve access to primary and preventative care through community partnerships, linking the resources of academic health centers with local communities. AHECs and HETCs have proven to be responsive and efficient models for addressing an ever-changing variety of community health issues.

However, AHECs and HETCs have not yet fully realized their potential to be a nationwide infrastructure for local training and information dissemination. In order

to realize that potential additional federal investment is required. That is why we are requesting an increase in funding to $40 million in fiscal year 2004 from $33.4 million in fiscal year 2003 for AHECs and $10 million in fiscal year 2004 from $4.4 million in fiscal year 2003 for HETCs.

PREPARED STATEMENT OF THE ASSOCIATION FOR PROFESSIONALS IN INFECTION CONTROL AND EPIDEMIOLOGY

Infection control professionals nationwide wish to thank Congress for its long-standing support of the Centers for Disease Control and Prevention (CDC), particularly with regard to strengthening the overall public health infrastructure in recent years. Although enhancements to our system have only just begun, these widespread efforts have already had a monumental impact on safeguarding the health of our nation. Indeed, if stronger infrastructure were not currently in place, we would find ourselves unable to adequately address the significant threat posed by Sudden Acute Respiratory Syndrome (SARS).

Emerging pathogens will continue to confound and challenge even the strongest of public health systems. Changes in human behavior, alterations to the environment, widespread antibiotic usage, and dramatic increases in international commerce and travel are factors contributing to the proliferation of drug resistance and resurgent and emerging microorganisms. It is imperative that we continue to enhance surveillance sites, strengthen epidemiological and laboratory response capabilities and support efforts to address emerging infectious disease on a global level.

Since the CDC is the primary entity responsible for safeguarding the public health, it is imperative that it be granted adequate resources to perform this monumental task. APIC recommends a fiscal year 2004 funding level of $7.9 billion and we hope that Members of Congress will take this into consideration during the appropriations process.

These enhancements will also help our nation to mobilize in the event of a bioterrorist act. However, the public health aspect is only part of the equation. We can no longer ignore the critical role of health care providers and health care facilities in our nation's response efforts. Hospitals and other care providers simply do not have the resources necessary to treat and contain medical cases that may occur as a result of a bioterrorist event or a new emerging pathogen. Additional resources are needed to fund supplies, special isolation rooms, specialists in infection control and disease prevention as well as educational programs to train all health care providers.

Facilities will succeed in this effort only through proper enhancements to their current systems and with adequate personnel and resources. Without this support, they cannot possibly take on these crucial public health-related activities on top of their current responsibilities. If the Health Resources and Services Administration (HRSA) is to be charged with distributing such funds, we would respectfully request that a much more realistic amount be allocated for this purpose.

We are seeking Congressional support in ensuring that federal funding reaches the level of the individual health care facilities as soon as possible. The health and safety of our citizens depend upon it.

FUNDING REQUEST

APIC is recommending the following funding levels for enhancing hospital infrastructure and bioterrorism preparedness.

—$3 billion for the Centers for Disease Control and Prevention (CDC) to continue building adequate public health infrastructure for responding to bioterrorism. This would increase the CDC Bioterrorism budget by $748 million over fiscal year 2002 and represents an increase of $1.4 billion over the President's fiscal year 2003 budget request.

—$620 million for the Health Resources and Services Administration (HRSA) to support the continued enhancement of bioterrorism readiness infrastructure at hospitals and other health care facilities. This would increase the HRSA Hospital Preparedness and Infrastructure Program by $485 million over fiscal year 2002, and is $102 million above the President's fiscal year 2003 budget proposal.

WHAT IS NEEDED?

Enhanced Infection Surveillance and Reporting.—for syndromes and diseases potentially associated with bioterrorism. Extensive surveillance is needed in emergency departments, admissions, and other affiliated sites, not just the primary care

facility, reported in real-time, and then tabulated/communicated back to appropriate recipients of data. This would include ambulatory care sites and ancillary sites. Surveillance tools need to be developed that facilitate rapid analysis and communication of suspected bioterrorism. These tools are best utilized when they are consistent in nature, user friendly, and wireless compatible.

Timely, Effective Communication with the Public Health Community.—The current infrastructure is insufficient; we need to develop and ensure rapid communication and electronic real-time reporting capabilities among the Federal, State, and Local levels. This includes the quick fine-tuning and deployment of NEDS or comparable systems. Current computer and communication systems are not technologically advanced to support the potential influx of data and provide feedback instantaneously. This also includes the necessary mobile devices to support collection of information and transmission to a centralized location/database. Communication needs to include smallpox vaccination data of health care providers and related smallpox Rapid Response Team members, available electronically throughout all jurisdictions.

Adequate Laboratory Services.—To ensure the availability of rapid, effective laboratory methodologies. In response to cost containment pressures, many facilities have chosen to outsource certain testing. This has a direct impact on the timeliness of results—a crucial factor in addressing a bioterrorist event. Furthermore, managed care constraints have forced practitioners to limit the ordering of tests required to document infectious agents which may impede our ability to detect a problem if there is one. The designated lab facilities that have requested status for testing need support to train personnel and or employ experienced personnel for handling and testing of specimens.

Adequate Airborne Infection Isolation Rooms (AIIRs) in All Facilities.—To ensure that facilities can isolate patients in environmentally appropriate conditions and still provide essential health care services. Development of such architectural plans should be done via appropriate multidisciplinary teams using the American Institute of Architects' 2001 "Guide for Design and Construction of Hospitals and Health Care Facilities." There is a great deal of disparity among facilities in regard to airborne isolation capability. Older facilities are often ill-equipped to triage, evaluate and admit patients—and may have very rudimentary, if any, airborne isolation rooms. Many facilities also have discrepancies in what type of patient even needs isolation and when to take them out, so they may report adequate or inadequate rooms based on their current interpretation of symptoms and/or syndromes. It is critical that every hospital has the capability to safely care for patients with potentially communicable conditions.

Education—To train clinicians on the signs, symptoms, and appropriate control measures for infectious agents likely to be used by terrorists. Education is paramount in training the personnel responsible for caring for patients to ensure the optimal safety of both patient and health care provider.

Adequate Health Care Personnel/Resources.—To ensure optimal patient care. We are currently in the midst of a major nursing shortage and there is a critical need to address this issue, as it will have drastic implications. We also need adequate and trained hospital epidemiologists and infection control professionals to implement and sustain the recommendations of the CDC and professional organizations at the grassroots level. These professionals are the community link to the public health system and are a vital partner in controlling and preventing the spread of contagion.

Strong Occupational Health and Safety Programs.—To ensure the safety and health of this critical workforce. Vaccination programs and other occupational health programs need to address liability, furlough and workers' compensation issues for health care facilities.

We also need to ensure continued funding and support of patient care activities that enhance patient safety and health care worker safety. Implementation of recommendations to isolate and contain new pathogens like SARS and other agents stress the budget of hospitals and ambulatory care centers due to the increased utilization and costs for personal protective equipment and supply management.

The Association for Professionals in Infection Control and Epidemiology (APIC) is a nonprofit professional organization comprised of some 12,000 members, most of whom work in health care facilities preventing and controlling infections. In the event of a bioterrorist attack, these health care professionals will be helping to lead the response for their facilities—caring for victims as well as controlling the spread of infection to others.

For more information, please contact Jennifer Thomas-Barrows, Director of Public Policy at 860–675–6869 jthomas@apic.org or Dale Dirks, Health & Medicine Counsel of Washington, 202–544–7499 dirks@hmcw.org

ASSOCIATION FOR PROFESSIONALS IN INFECTION CONTROL AND EPIDEMIOLOGY

APIC is a multi-disciplinary, voluntary, international organization, which promotes wellness and prevents illness and infection world-wide by advancing health care epidemiology through education, collaboration, research, practice, and credentialing.

PREPARED STATEMENT OF THE PULMONARY HYPERTENSION ASSOCIATION

SUMMARY OF FISCAL YEAR 2004 RECOMMENDATIONS

—$1 million within the Centers for Disease Control and Prevention (CDC) for a pulmonary hypertension awareness and education program.
—A 10 percent increase for the National Heart, Lung and Blood Institute (NHLBI).
—$30 million for the Health Resources and Services Administration's (HRSA) "Gift of Life Donation Initiative."

Mr. Chairman, thank you for the opportunity to submit written testimony regarding fiscal year 2004 appropriations for the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and Health Resources and Services Administration (HRSA).

PH is a rare disorder involving both the heart and the lungs. The walls of the blood vessels that supply the lungs thicken and often constrict, making them unable to carry normal amounts of blood. The heart works harder to compensate and eventually can't keep up. Life is threatened. Currently, there is no cure. Symptoms of pulmonary hypertension include shortness of breath with minimal exertion, fatigue, chest pain, dizzy spells and fainting.

When PH occurs in the absence of a known cause, it is referred to as primary pulmonary hypertension (PPH). This term should not be construed to mean that because it has a single name it is a single disease. There are likely many unknown causes of PPH.

Secondary pulmonary hypertension (SPH) means the cause of the disease is known. Common causes of SPH are the breathing disorders emphysema and bronchitis. Other less frequent causes are scleroderma, CREST syndrome and systemic lupus. In addition, the use of diet drugs can lead to the disease.

While new treatments are available, unfortunately, PH is frequently misdiagnosed and often progresses to late stages by the time it is detected. Although PH is chronic and incurable with a poor survival rate, the new treatments becoming available are providing a significantly improved quality of life for patients. Recent data indicates that the length of survival is continuing to improve, with some patients able to manage the disorder for 20 years or longer.

Eleven years ago, when three patients who were searching to end their own isolation founded this organization, there were less than 200 diagnosed cases of this disease. It was virtually unknown among the general population and not well known in the medical community. They soon realized that this was not enough and as membership began to grow—driven by a newsletter written by patients and distributed by doctors—and as a community began to form, an 800 number support line was launched, support groups were established, a Scientific Advisory Board (SAB) was formed, a Patient's Guide to Pulmonary Hypertension was written, and a web site was launched.

Today, PHA includes:
—Over 4,500 patients, family members, and medical professionals.
—An international network of over 100 support groups.
—An active and growing patient telephone helpline.
—A new and fast-growing research fund. (A cooperative agreement has been signed with the National Heart, Lung, and Blood Institute to jointly create and fund five, five-year, mentored clinical research grants and PHA has awarded seven Young Researcher Grants.)
—A host of numerous electronic and print publications, including the first medical journal devoted to pulmonary hypertension—published quarterly and distributed to all cardiologists, pulmonologists and rheumatologists in the United States.

CENTERS FOR DISEASE CONTROL AND PREVENTION

PHA applauds the subcommittee for its leadership in encouraging CDC to initiate a professional and public PH awareness campaign. Currently, we are working with officials at the CDC to establish this important program that will better inform

health care professionals and the general public about PH, its symptoms, and treatment options.

PHA knows that Americans are dying because of a lack of awareness of both pulmonary hypertension and recent advances in research and treatments. Most particularly, this is true among underserved populations. These are the least likely and the least able to see the three and four doctors it often takes to get a correct diagnosis. We believe that activities proposed below need to include special focus on reaching underserved populations and their medical services.

The following is a description of the specific initiatives we hope to launch in collaboration with CDC.

(1) Increasing awareness and understanding of PH among primary care physicians is critically important, because these practitioners are usually the first point of contact for PH patients. If the primary care doctor misses the symptoms, then the chance for early diagnosis depends upon the intuition and persistence of the patient. They have a chance, if they aggressively pursue diagnosis by trained and aware specialists. If they are not aggressive, or if they are in a health plan that requires their general practitioner to prescribe the referral, they are more likely to go undiagnosed until it is too late to control their illness. To increases awareness we propose to launch the following:

—Written and video diagnostic tools for placement on the Internet.

—Working with state health departments and clinic administrators to develop information for mailing to primary care physicians, medical schools and medical centers in the United States drawing their attention to the new web resources.

—A simplified and visually attractive print version of the proper diagnostic procedures, which will be targeted to primary care physicians, public health clinics, medical schools, and medical centers in the United States.

—Advertising in publications general practitioners and public health professionals are likely to read. The emphasis will be the importance of early diagnosis and the ease of accessing diagnostic tools via the Internet.

—Improvements to an already produced CD–ROM that explains pulmonary hypertension from a variety of perspectives. We would like to make these available to the medical community and patients through our web site on an as requested basis and at conferences and through targeted mailings.

(2) Due to the advancements in treatment for PH, it is important that we also focus on educating cardiologists and pulmonologists. Our strategies for reaching cardiovascular specialists include:

—Expansion of the first Pulmonary Hypertension Journal focused on educating a cardiologists and pulmonologists on issues related to the diagnosis and treatment of the illness.

—Placement of additional detailed information on the illness on the web. The PH Journal and other publications will promote this availability.

—Expansion of the medical section of PHA's international conference on pulmonary hypertension (the largest PH conference in the world).

—Expansion of PHA's Pulmonary Hypertension Resource Network. This program is focused on increasing awareness and knowledge of PH among nurses, respiratory therapists, technicians and pharmacists through peer education.

(3) Finally, PHA is committed to increasing PH awareness among the general public through the development of the following initiatives:

—A series of 10, 15, and 30 second public service announcements on PH. These PSAs will be in both audio and video form.

—A PH media relations manual.

—An organ donation and transplant listing Awareness Campaign (unfortunately, many PH patients die before finding a suitable organ donor).

—Expansion of awareness and information activities on PHA's web site.

We look forward to working with the CDC to implement these and other initiatives aimed at increasing awareness of PH in the United States and throughout the world. For fiscal year 2004, we encourage the subcommittee to continue to support the mission of the CDC with an overall appropriation of $7.9 billion. Moreover, we urge you to provide $1 million within CDC's Cardiovascular Disease program for a PH awareness campaign.

NATIONAL HEART, LUNG AND BLOOD INSTITUTE

Mr. Chairman, PHA commends the leadership of the National Heart, Lung and Blood Institute (NHLBI) for its support of PH research. Two years ago, two separate groups of scientists funded by NHLBI simultaneously identified a genetic mutation associated with primary pulmonary hypertension.

The two groups independently reported that defects in the BMPR2 gene, which regulates growth and development of the lung, are associated with PPH. The defects in the gene lead to the abnormal proliferation of cells in the lung characteristic on PPH.

Although both studies suggest that only one gene is involved in PPH, neither group identified the defects in BMPR2 as the sole cause of PPH. In addition, since many people without a known family history of PPH get the disease, both groups suggested that other factors may interfere with control of the tissue growth. Now that we have pinpointed a gene, we can focus on learning how it works. Hopefully, that information will enable researchers to devise better treatments and perhaps eventually a preventive therapy or cure.

We were pleased and excited that NHLBI recently convened a meeting of leading PH researchers to chart the future of PH research. We appreciate the agency's commitment to advancing research to better understand and ultimately cure this disease.

Mr. Chairman, PHA would like to thank you and the subcommittee for your leadership in support of funding for the National Institutes of Health. Moreover, we would like to thank the subcommittee for the inclusion of committee recommendations on PH research at NHLBI in the fiscal year 2003 Senate L-HHS report. For fiscal year 2004, PHA joins with the Ad Hoc Group for Medical Research Funding in supporting a 10 percent increase for NHLBI.

GIFT OF LIFE DONATION INITIATIVE AT HRSA

Mr. Chairman, PHA commends the leadership of Secretary Thompson on the success of his "Gift of Life Donation Initiative." Currently, there are three drugs that PH patients can be prescribed to help improve the quality of life with PH. Eventually, many patients must move toward lung or heart and lung transplantation. PH is a difficult to diagnose illness and while patients often list soon after diagnosis, for many PH patients it is too late. This why PHA is developing the Bonnie's Gift Project.

Bonnie's Gift was started in memory of Bonnie Dukart, one of PHA's most active and respected leaders. Bonnie was a PH patient herself. She battled with PH for almost 20 years until her death in 2001 following a double lung transplant. Prior to her death, Bonnie expressed an interest in the development of a program within PHA related to transplant information and awareness. PHA will use Bonnie's Gift as a way to disseminate information about PH, the importance of early listing, the importance of organ donation to our community and organ donation cards.

Consequently, PHA applauds the administration for its "Gift of Life Donation Initiative," which is designed to increase organ donation rates throughout the country. We look forward to working with the "Gift of Life Donation Initiative" to increase awareness of the importance of organ donation among the PH community, the medical community and the public. Mr. Chairman, PHA supports $30 million in fiscal year 2004 for HRSA's "Gift of Life Donation Initiative."

CONCLUSION

Mr. Chairman, once again thank you for the opportunity to present the views of the Pulmonary Hypertension Association. We look forward to continuing to work with you and the subcommittee to improve the lives of pulmonary hypertension patients. If you have any questions or would like additional information, please do not hesitate to contact me or the PHA National Office in Silver Spring, Maryland (301) 565–3004 x101.

PREPARED STATEMENT OF THE SOCIETY OF TEACHERS OF FAMILY MEDICINE, THE ASSOCIATION OF DEPARTMENTS OF FAMILY MEDICINE, THE ASSOCIATION OF FAMILY PRACTICE RESIDENCY DIRECTORS, AND THE NORTH AMERICAN PRIMARY CARE RESEARCH GROUP

Mr. Chairman, on behalf of the Society of Teachers of Family Medicine, the Associations of Departments of Family Medicine, the Association of Family Practice Residency Directors, and the North American Primary Care Research Group, we of would like to thank you for the opportunity to provide this statement for the record on behalf of funding for family medicine training, and the Agency for Health Care Research and Quality (AHRQ).

Mr. Chairman, the Organizations of Academic Family Medicine would like to thank you for this committee's commitment to these programs. We appreciate the funding included in the fiscal year 2003 appropriations funding bill, especially in light of fiscal constraints. Family medicine training programs are funded under Section 747, the Primary Care Medicine and Dentistry cluster, of Title VII of the Public Health Service Act. We ask that you continue your support for family medicine training, and bring the appropriations level for section 747, the Primary Care Medicine and Dentistry Cluster, up to $169 million for fiscal year 2004, of which $96 million is needed for family medicine. This statement is designed to show the committee how its investment is paying off. This statement will discuss the success of these programs and include recommendations about what still needs to be done. As you look at all the opportunities you have to fund domestic health programs you need to be able to make judgments about the value and utility of these programs. We have been asked in various venues to show proof that these funds actually do what they are designed to do. We must show that this money makes a difference. In this statement we intend to do just that. In addition, we believe Congress also needs to understand the unmet needs that exist in our nation—needs Health Professions programs can successfully help address.

President's Budget Request for Fiscal Year 2004 Once Again Zeros Out Primary Care Funding

The President's budget zeroes out funding for the Primary Care Medicine and Dentistry cluster. In addition, the proposal includes only $109 million for all of the Health Professions programs (Title VII and VIII), a sharp cut of almost 75 percent from the fiscal year 2003 level of $423.8 million. The budget also claims these programs are ineffective, although we believe the analysis used by OMB to determine this is extremely flawed. While OMB has criticized the entire group of 21 health professions programs taken together as lacking clear purpose, the goals of those specific programs under Section 747 are very clear. According to several studies (see below), Title VII dollars in general, and family medicine funding in specific have proven effective in addressing several major health professions problems.

Family Medicine Training Programs Are A Success

First, let's take a look at health professions training—specifically family medicine training. These programs are producing the outcomes that Congress has requested. In a current study (Family Medicine, June 2002), the Robert Graham Center For Policy Studies In Family Practice and Primary Care has shown that federal funding through Title VII of family medicine departments, predoctoral programs, and faculty development has made a difference. The study shows that:

—All three types of grants made a difference in producing more family physicians, and more primary care doctors

—Predoctoral and department development grants made a difference in producing more primary care doctors serving in rural areas, and more primary care doctors serving in primary care he alth professional shortage areas.

—Sustained funding during the years of medical school training had more positive impact than intermittent funding.

We must conclude from this data that this funding means that thousands of physicians are making different career choices, choices that positively affect millions of patients in underserved areas and in primary care. Moreover, if this money were to "go away" fewer students would be making these career choices.

Other Indicators Of Success

The federal government's independent General Accounting Office (GAO) has also shown that this money works. The GAO, in two reports in 1994, addressed the question of how do we know Title VII money is well spent? A July 1994 report, states that "the programs were important for funding innovative projects and providing 'seed money' for starting new programs. For example, Title VII was considered important in the creation *and maintenance* [emphasis added] of family medicine departments and divisions in medical schools." In another report, the GAO states in October 1994 that "students who attended schools with family practice departments were 57 percent more likely to pursue primary care." In addition, the report goes on to say that "students attending medical schools with more highly funded family practice departments were 18 percent more likely to pursue primary care and students attending schools requiring a third-year family practice clerkship were [also] 18 percent more likely to pursue primary care." The money spent on Section 747 of Title VII is directly targeted in these areas.

Loss of Funding for Family Medicine Training Would Cause Tremendous Impact on Service to the Underserved

Data show that if production of family physicians was to fall, the impact on the nation's underserved would be great. The fewer the number of family physicians produced, the greater the number of new health professional shortage areas, or HPSAs. This holds true even in comparison with the combined loss of internists, pediatricians and obstetrician/gynecologists. The United States relies on family physicians unlike any other specialty. Without family physicians an additional 1332 of the United States' 3082 urban and rural counties would qualify for designation as primary care HPSAs. This contrasts with an additional 176 counties that would meet the criteria if all internists, pediatricians, and ob/gyns in aggregate were withdrawn. The bottom line is that without family physicians 1332 counties would qualify for primary care HPSA designation vs. 176 counties if other primary care specialists were withdrawn.

What Is The Unmet Need? Why Must We Continue To Fund And Grow These Programs?

According to a study by Politzer, et al (*The Journal of Rural Health,* Winter, 1999) Title VII funding is key to ending HPSAs. This funding has led to the time needed for HPSA elimination to decrease to 15 years. Doubling the funding for these programs would decrease the time for HPSA elimination to as little as 6 years. According to the study, without this funding, not only would HPSAs not be eliminated, but the number of shortage areas would continue to grow. Moreover, success has been attained by an allocation of funds more favorable to family medicine than the other two primary care specialties. Title VII funding has indeed accomplished many of the objectives for which it was designed:

—Funding of in novative projects
—Providing "seed money" for the start-up of new projects
—The creation and maintenance of departments of family medicine in the nation's medical schools
—The development of 3rd year clerkships in family medicine
—The increase in students selecting primary care residencies from those schools with funded family medicine departments and 3rd year clerkships
—The increased rate of graduates from Title VII funded projects entering practice in medically underserved areas (MUAs), with a resultant reduction in the time required for Health Professions Shortage Area (HPSA) elimination

Section 747 Advisory Committee Recommends Higher Funding

In 1998, Congress established an Advisory Committee to review and make recommendations on Section 747. The Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) recently released its recommendations to Congress and the Secretary of the Department of Health and Human Services. The first of six recommendations urges greatly expanding federal support for Section 747 to $198 million. The Committee notes the growing need for primary care providers, as well as the success of Title VII funded programs. The training enterprise that does not value primary care either financially or otherwise is a key part of the problem. Title VII funds that support the infrastructure and stability of family medicine departments in medical schools have to be sustained in order to keep producing the current levels of primary care physicians and, more specifically, those who will practice in rural and other underserved areas. Clearly, the programs of Title VII are on the right track toward meeting the health care challenges of the 21st century. So, while we believe that current funding must be maintained, more needs to be done.

Proposed Performance Measures Need to be Redefined

The current proposed performance measures are neither measurable nor appropriate. Consequently, assessments of effectiveness of the programs based on these measures are highly flawed. For example, the target set for the proportion of underrepresented minorities (URMs) and disadvantaged students in health professions funded programs is set at 40 percent for 2004, even though only 12.5 percent of current medical school graduates are URMs, and data on disadvantaged backgrounds is not routinely, or accurately collected. The concept of disadvantaged background varies based on income related to family size, or is based on a vague—non-quantifiable—notion of persons growing up in environments that don't prepare them to enter health professions schools. In 2000 approximately 12.5 percent of the medical degrees awarded in the United States went to underrepresented minorities. For all of health professions minority representation has risen from 8.3 percent in 1985 to 11.7 percent in 2000. Given this data, it's simply unrealistic to expect any program

to increase its minority representation in one year from 12.5 percent to 25 or 40 percent.

Primary Care Training Programs React Quickly to Emerging Health Challenges

Title VII dollars have created an infrastructure that allows educational programs to respond to contemporary health care issues. Specifically, the ACTPCMD report states that:

"Investment in education to provide primary care has effects that touch the largest number of people in the country. No other group of health care providers can exert such a broad influence on the kind and quality of health care in the United States. Primary care training programs are ideally positioned to react quickly to meet ever-changing health care needs and issues, whether they are related to HIV/AIDS, growing numbers of elderly with chronic illnesses, implications of the modern genetics revolution, the threat of bioterrorism, or other issues that will continue to emerge and demand rapid educational intervention. Thus, this infrastructure is uniquely able to play a pivotal role in bringing emerging issues in health care to the population at large."

Mr. Chairman, we know that this committee has to weigh the value of funding various programs against each other. We hope that the evidence we have presented here will bring the committee to the conclusion that funding spent on these programs would bring value for the money and would be money exceptionally well spent.

FUNDING FOR THE AGENCY FOR HEALTH CARE RESEARCH AND QUALITY (AHRQ)

Mr. Chairman, once again, we thank you and this committee for increasing funding for this important agency. It is apparent that the key federal agency available to fund primary care research is the Agency for Healthcare Research and Quality (AHRQ). In it's recent rea uthorization, Congress established within the Agency a Center for Primary Care Research to "serve as the principal source of funding for primary care practice research in the Department of Health and Human Services." The statute defined primary care research as research that "focuses on the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

Funding Request For AHRQ

We recommend appropriations of $390 million for the Agency for Healthcare Research and Quality (AHRQ) in fiscal year 2004. AHRQ conducts primary care and health services research geared to physician practices, health plans and policymakers that helps the American population as a whole.

President's Budget Request for Fiscal Year 2004 Cuts AHRQ Funding

The President's budget includes $279 million for AHRQ, a cut of about $24 million, from the current funding level of $303.7 million. If this budget request of $279 million were enacted, a reduction of funding of over 8 percent would result. Under this scenario, AHRQ would be unable to award any new non-patient safety grants in fiscal year 2004 and existing non-patient safety grants would have to be cut by 15 percent. We are particularly grateful for this committee's efforts last year when the President's proposed budget would have reduced AHRQ by $48 million. Your restoration of AHRQ's funding in the final funding bill was critical in continuing research needed to improve health care quality, access, and financing in the United States. Now as you develop your fiscal year 2004 budget, we ask that you not only maintain, but enhance funding for this critical agency.

What Does AHRQ Do?

AHRQ's three goals are to (1) improve physician practice and Americans' health outcomes, (2) improve the quality of health care (e.g., patient safety), and (3) improve the health care system (e.g., increase access and reduce costs). In brief, AHRQ "helps to improve the health and health care of the American people." (AHRQ report, March, 2001).

How Does AHRQ Meet Its Goals?

AHRQ translates research findings from basic science entities like the National Institutes of Health into information that doctors can use every day in their practice with their patients. Another key function of the agency is to support research on the conditions that affect most Americans.

AHRQ Translates Research into Everyday Practice

Congress has provided billions of dollars to the National Institutes of Health, which has resulted in important insights in preventing and curing major diseases. AHRQ takes this basic science and produces information that physicians can use every day in their practices. AHRQ also distributes this information throughout the health care system. In short, AHRQ is the link between research and the patient care that Americans receive. An example of this link is basic science research showing that beta blockers reduce mortality. AHRQ supported research to help physicians determine which patients with heart attacks would benefit from this medication.

AHRQ Supports Research on Conditions Affecting Most Americans

Most Americans get their medical care in doctors' offices and clinics. However, most medical research comes from the study of extremely ill patients in hospitals. AHRQ studies and supports research on the types of illness that trouble most people. AHRQ looks at the problems hat bring people to their doctors every day—not the problems that send them to the hospital. For example, AHRQ supported research that found older antidepressant drugs are as effective as new antidepressant medications in treating depression, a condition that affects millions of Americans.

Institute of Medicine Recommends $1 Billion for AHRQ

The Institute of Medicine's report, *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001), recommended $1 billion a year for AHRQ to "develop strategies, goals, and actions plans for achieving substantial improvements in quality in the next 5years . . ." The report looked at redesigning health care delivery in the United States. AHRQ is a linchpin in retooling the American health care system.

RECOMMENDATIONS FOR FAMILY MEDICINE TRAINING AND RESEARCH

The Organizations of Academic Family Medicine have two main recommendations for the fiscal year 2004 Labor/HHS Appropriations bill. They are as follows:

—We ask that you continue your support for family medicine training, and bring the appropriations level for section 747, the Primary Care Medicine and Dentistry Cluster, up to $169 million for fiscal year 2004, of which $96 million is needed for family medicine.

—In order to support critical practice-oriented primary care research, and to ensure that existing grants and contracts will not be cut, we are asking that the Agency for Healthcare Research and Quality be funded at $390 million.

PREPARED STATEMENT OF THE MARCH OF DIMES BIRTH DEFECTS FOUNDATION

The March of Dimes is pleased to have the opportunity to submit testimony on behalf of its 1500 staff and over 3 million volunteers, and share with you some of the Foundation's federal funding priorities for fiscal year 2004. As you may know, the March of Dimes is a national voluntary health agency founded in 1938 by President Franklin D. Roosevelt to prevent polio. Today, the Foundation works to improve the health of mothers, infants and children by preventing birth defects and infant mortality through research, community services, education, and advocacy. The March of Dimes is a unique partnership of scientists, clinicians, parents, members of the business community, and other volunteers affiliated with 54 chapters in every state, the District of Columbia and Puerto Rico.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

National Center on Birth Defects and Developmental Disabilities

Of the four million babies born each year in the United States, approximately 150,000 are born with one or more serious birth defects. Birth defects are the leading cause of infant mortality accounting for more than 20 percent of all infant deaths and are responsible for about 30 percent of all pediatric hospital admissions. In addition, birth defects are the fifth-leading cause of years of potential life lost and contribute substantially to childhood morbidity and long-term disability. Because the causes of about 70 percent of all birth defects are unknown, the public continues to be anxious about whether environmental pollutants cause birth defects, developmental disabilities, or other adverse reproductive outcomes. The public also has many questions about whether various occupational hazards, dietary factors, medications, and personal behaviors cause or contribute to birth defects.

The National Center on Birth Defects and Developmental Disabilities (NCBDDD) at the CDC works to improve the health of children and adults by preventing the occurrence of birth defects and developmental disabilities; and promoting health and wellness among children and adults with disabilities. The March of Dimes urges this Subcommittee to increase funding for the Center to $125 million in fiscal year 2004. This modest increase will provide the resources necessary to expand many of the important activities supported by the Center. Of particular interest to the March of Dimes is the prevention of birth defects for which causes have already been identified and the identification of causes for those which have not. A comprehensive program that includes surveillance, research and prevention activities is being administered by the National Center on Birth Defects and Developmental Disabilities (NCBDDD). A modest increase of $15.9 million in funding for three programs is a vital step to making progress in the fight against birth defects.

Surveillance: State Cooperative Agreements to Improve Birth Defects Tracking

NCBDDD provides funding to states to develop, implement, and/or expand community-based birth defects tracking systems, programs to prevent birth defects, and activities to improve access to health services for children with birth defects. Surveillance forms the backbone of a vital, functional and responsive public health network. CDC is now supporting cooperative agreements with 28 states, each funded between $100,000 and $200,000 a year for each of three years. The March of Dimes encourages the Subcommittee to add $3.4 million ($7.5 million total funding) to state-based birth defects surveillance activities. As you may be aware, resources have not been adequate to fund all the states seeking CDC assistance. These additional resources are needed to help all the states seeking CDC assistance and to increase the level of assistance to states already receiving support.

Research: Regional Centers for Birth Defects Research and Prevention

NCBDDD funds 10 regional Centers for Birth Defects Research and Prevention, each receiving approximately $900,000 per year, to conduct epidemiological research on birth defects. The centers are located in Arkansas, California, Georgia, Iowa, Massachusetts, New Jersey, New York, North Carolina, Texas, and Utah. These centers identify cases and obtain data for inclusion in the National Birth Defect Prevention Study, the largest case-control study of birth defects ever conducted. Now the centers are using this data for studies on the effectiveness of various methods for the primary prevention of birth defects, the teratogenicity of various drugs, the environmental causes of birth defects and the genetic factors that make people susceptible to environmental causes of birth defects, the behavioral causes of birth defects, and the costs of birth defects. The March of Dimes encourages the Subcommittee to add $10 million ($16.3 million total funding) to fund all these areas of promising research and continue operating all the centers.

Prevention: Folic Acid Education Campaign

NCBDDD is conducting a national public and health professions education campaign designed to increase the number of women taking folic acid daily. Each year, an estimated 2,500 babies are born with neural tube defects (NTDs), birth defects of the brain and spinal cord, including anencephaly and spina bifida. CDC estimates that up to 70 percent of NTDs could be prevented if all women of childbearing age consume 400 micrograms of folic acid daily, beginning before pregnancy. Significant progress has been made and the rates of spina bifida have declined 31 percent. With increased funding and in collaboration with the National Spina Bifida Program, which also has a prevention focus, this campaign could be expanded to reach more women of childbearing age and their health care providers. The March of Dimes recommends an appropriation of at least $5 million for fiscal year 2004 to promote this lifesaving intervention.

NATIONAL INSTITUTES OF HEALTH

The March of Dimes joins the research community in recommending a 10 percent increase in funding for the National Institutes of Health (NIH), which would bring total funding to $30 billion. A sustained investment in medical research is vital to solving many of the diseases and conditions affecting mothers and children. Specifically, and of particular interest to the March of Dimes, are the research activities at the National Institute of Child Health and Human Development.

National Institute for Child Health and Human Development

The mission of National Institute for Child Health and Human Development (NICHD) is closely aligned with that of the March of Dimes. The Foundation recommends an overall increase of 10 percent for NICHD. With this increase in fund-

ing, NICHD could expand research in several areas that are crucial to the health of mothers and children. Additional funds would permit expansion of research into the causes of birth defects, and also the causes of prematurity. Increased funding would also enable NICHD to accelerate the timetable for implementing a much-needed analysis of environmental influences on child health and development that will be conducted as part of the National Children's Study authorized by the Children's Health Act of 2000.

Pre-term labor and delivery is the number one problem in obstetrics today and a serious problem in pediatrics. It is the leading cause of neonatal mortality, and many babies born prematurely have serious physical and mental disabilities, such as cerebral palsy, mental retardation, chronic lung disease, and vision and hearing loss, that last a lifetime. Prematurity is also a growing problem. Between 1991 and 2001, the annual percentage of newborns delivered preterm in the United States increased from 10.8 percent to 11.9 percent. More than 476,000 babies in the United States-nearly 12 percent of all US babies-were born prematurely in 2001. Prematurity is also one of the clearest indices of racial disparities. Rates of preterm birth vary significantly by race and ethnicity. In 2001, rates for blacks were highest among all racial and ethnic subgroups—17.5 percent as compared to 11 percent for white Americans.

The March of Dimes recommends increased funding of at least $50 million over the next five years to boost prematurity-related research at NICHD, with particular emphasis on expanding the collaborative networks for Maternal-Fetal Medicine Units and Neonatal Research. More funds are needed to reveal the underlying causes of preterm delivery, to identify prevention strategies and improve the treatment and outcomes for infants born preterm.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

Newborn Screening

One of the great advances in preventive medicine has been the introduction of newborn screening. Newborn screening is a public health activity used to identify certain genetic, metabolic, hormonal and/or functional conditions in newborns. As the Committee members know, such disorders, if left untreated, can cause death, disability, mental retardation and other serious problems. Although nearly all babies born in the United States undergo newborn screening tests for genetic birth defects, the number and quality of these tests vary from state to state. The March of Dimes recommends that every baby born in the United States receive, at a minimum, a core set of 10 screening tests.

The March of Dimes proposes an appropriation of $25 million to support HRSA's work with states to implement the heritable disorders (newborn screening) program authorized in Title XXVI of the Children's Health Act of 2000. This program is designed to strengthen states' newborn screening programs; to improve states' ability to develop, evaluate, and acquire innovative testing technologies; and to establish and improve programs to provide screening, counseling, testing and special services for newborns and children at risk for heritable disorders.

Thank you for the opportunity to testify on the programs of highest priority to the March of Dimes. The staff and volunteers of the March of Dimes look forward to working with members of the Subcommittee to improve the health of mothers, infants and children.

PREPARED STATEMENT OF THE AMERICAN DENTAL EDUCATION ASSOCIATION (ADEA)

ADEA is the premier national organization that speaks for dental education. It is dedicated to serving the needs of all 56 U.S. dental schools, 731 U.S. dental residency programs, 266 dental hygiene programs, 6,150 dental assisting programs, and 24 dental laboratory technology programs, as well as the 11,332 full- and part-time dental school faculty, more than 5,060 dental residents and the nation's 37,300 dental and allied dental students. It is at dental education institutions that future practitioners and researchers gain their knowledge; the majority of dental research is conducted; and significant dental care is provided to many underserved low-income populations, including individuals covered by Medicaid and the State Children's Health Insurance Program (SCHIP).

Dental schools across the country are doing their part to increase access to oral health care for underserved populations and to build upon research for the good of

all. According to a study conducted by the American Dental Association,[1] nearly half of all patients treated at dental school clinics are covered by public assistance with a majority of patients having an income of $15,000 or less. Examples of the commitment dental education is making to improve access and build the research capacity can be found in the states such as Pennsylvania, Iowa, Texas, Mississippi, and South Carolina include:

—In Pennsylvania, the University of Pittsburgh School of Dental Medicine provides state-mandated dental screenings for kindergarten, grades 3 and 7 at the Wilkinsburg School District; while the Temple University School of Dentistry provides services at its school-based dental clinic at Roberto Clemente Middle School and at its rural dental clinic in Wellsboro, in addition to providing dental and nutritional services to HIV/AIDS patients at its Rosenthal Clinical Center.

—Iowa's large elderly population makes it imperative that students build skills for treating older adults. Students at the University of Iowa College of Dentistry spend 25 percent of their senior year providing oral health care in extramural programs, largely in community-based clinics.

—In Texas, the state's three dental schools are successful in increasing access to oral health care. The University of Texas Health Science Center at San Antonio Dental School provides emergency care to indigent patients and provides presurgical treatment to patients undergoing organ transplants and their Department of Pediatric Dentistry staffs Santa Rosa Hospital's dental clinics, which provides care to both patients being treated for cancer, birth defects and other life-threatening problems.

The Baylor College of Dentistry is the largest single provider of oral health care services in the Dallas/Fort Worth area and the University of Texas Health Science Center at Houston Dental Branch is one of the primary sources of dental care for the city's rapidly growing underserved populations.

—Mississippians directly benefit from primary care dentistry training programs with more than 70 percent of all of the University of Mississippi School of Dentistry's graduates staying in state to practice. They practice in 68 of the state's 82 counties, and many are in small towns and rural areas where the need is greatest.

—Through funding from the National Institute of Health (NIH) National Center for Research Resources the Medical University of South Carolina College of Dental Medicine established a Center of Biomedical Research Excellence in Oral Health that addresses two health issues in which significant disparities exist nationally and in the state—the relationship between oral health and overall health (focusing on patients with diabetes) and oral cancer.

Congress' commitment to sustained federal funding is one of the keys that make these kinds of successes happen. Federal funding unlocks the doors of promise in America—the promise of access to health care for underserved communities, the promise to students who seek to achieve their dream of becoming a dentist, and the promise that federal investments made in health research will be implemented to benefit all people in the United States.

Several federal programs play a significant role in responding positively to the challenges of oral health disparities, dental education, and diversity in the workforce that are outlined in the Surgeon General's Report.[2] The Report alerts Congress and the nation to recognize the importance of oral health and the deleterious effects of inadequate oral health care. It calls attention to the fact that the burden of oral diseases and conditions is disproportionate among the U.S. population. Reports from the General Accounting Office and the National Governors Association corroborate these findings.

Other significant challenges exist with regard to the infrastructure of dental education and the oral health delivery system. For instance:

—The ratio of professionally active dentist-to-population is projected to continue declining, from its peak of 60:100,000 in 1994 to 54:100,000 in 2020.[3] As a sizable portion of the U.S. population has difficulty availing itself of needed or wanted oral health care, the decline is creating concern as to the capability of the dental workforce to meet emerging demands of society and provide services efficiently.

—Dental education debt has increased, affecting both career choices and practice locations. In 2002, about 59 percent of individuals who had educational debt graduated with debt over $100,000, and nearly 30 percent had debt greater

[1] "Study of Dental School Facilities and Programs," American Dental Association, August, 1999.

[2] "U.S. Surgeon General Report: Oral Health in America", 2000.

[3] "Future of Dentistry," American Dental Association, Health Policy Resources Center, 2001.

than $150,000. The average educational debt for students with such debt was $122,491.

—A crisis in the number of faculty and researchers threatens the quality of dental education, oral, dental, and craniofacial research, and, ultimately, access to necessary oral health care for Americans. Presently, there are approximately 350 vacant faculty positions at U.S. dental schools. The issue of access to care cannot be addressed successfully without increasing the numbers of dentists entering academia and research, and

—Lack of diversity and the number of under-represented minorities in the oral health professions is disproportionate to their distribution in the population at large. Their low rate of applications and enrollment in dental schools forebodes their continued under-representation in academia, research, and the dental workforce.

Several of the important health education, research and training programs for which we are making recommendations will be decimated if the Administration's proposal to eliminate their funding is enacted. It is imperative that Congress appropriate adequate funding for their continuation and enhancement. They are essential to the health and vitality of the nation. Consequently, the American Dental Education Association requests:

(1) $15 million to fund the General Dentistry and Pediatric Dentistry Residency Training programs

The ADEA strongly objects to the Bush Administration's elimination of funding for the Title VII general dentistry and pediatric dentistry residency programs. Eliminating funding for these programs runs contrary to the Advisory Committee on Training in Primary Care Medicine and Dentistry that recommended to the Secretary of HHS [4] that Title VII be "expanded substantially" with an "increased budget level."

General and pediatric dentistry residency training programs are effective in increasing access to care while providing dentists with the skills and clinical experiences needed to deliver a broad array of oral health services to patients, including Medicaid and SCHIP populations, as well as medically compromised patients.

Pediatric dentistry is the dental counterpart to general pediatric medicine. Currently, there are only 3,800 pediatric dentists in the country; some states have fewer than 10. Pediatric dentistry training positions have only recently begun to expand as a direct result of federal investment.

Dentists who complete primary care dental residency training are better able to address a wide variety of oral health maladies without referring patients to specialists. Each year approximately 165 students enter one of the nation's 59 accredited pediatric dentistry programs, while 1,484 students enter one of the country's 313 accredited general dentistry programs.

(2) $135 million to fund the Health Professions Education and Training Programs for Minority and Disadvantaged Students, including $3 million for the Faculty Loan Repayment Program

The President's budget proposes to eliminate funding for programs that have been successful in creating the basic infrastructure for educating a primary care workforce to help care for vulnerable populations. However, the infrastructure that has been established by previous federal investment requires sustained and increased support to meet the challenges of diversifying the health care workforce, addressing student indebtedness, eliminating faculty shortages, and eliminating oral health care disparities in underserved communities.

The Centers of Excellence (COE) and the Health Careers Opportunity Program (HCOP) play critical roles in preparing, recruiting and retaining disadvantaged students in predoctoral health professions schools. As the U.S. population becomes increasingly multicultural, so must the faculties and students in academic dental institutions. The federally funded COE and HCOP programs are key in assisting health professions schools to prepare disadvantaged and minority students for entry into dental, medical, pharmacy, and other health professions. The federal government has a responsibility to help to develop a culturally competent workforce that will reduce health care disparities related to cultural factors.

Among the four dental schools that have an HCOP grant is the University of California at San Francisco School of Dentistry. Its program collaborates with three high schools, four universities, and one community based organization. The program provides recruitment activities, preliminary education during the academic year and

[4] "Comprehensive Review and Recommendations: Title VII, Section 747 of the Public Health Service Act," November 2001.

summer, financial aid information dissemination, facilitating entry activities, counseling, mentoring and other services to develop a more competitive applicant pool of students to enter and complete training in the field of dentistry.

If the President's budget request were enacted, the Faculty Loan Repayment Program (FLRP) that assists dentists and other qualified clinicians to enter academia would be eliminated. It is the only federal program that endeavors to increase the number of economically disadvantaged faculty members. The program takes on additional significance in light of current and predicated faculty shortages. ADEA urges Congress to increase funding for the program and also broaden eligibility for the Faculty Loan Repayment Program to faculty members with qualifying student loan debt, regardless of their background.

(3) $19 million, a modest increase of $5.5 million over the fiscal year 2003 level, to fund the Ryan White HIV/AIDS Dental Reimbursement Program of the Ryan White CARE Act (Part F)

Federal support for this program increases access to oral health services for HIV/AIDS patients, while, at the same time, providing dental students and residents the education and training necessary to deliver oral health care to this population. This important program accomplishes two appropriate objectives of the federal government—service to patients of limited means and education of future practitioners.

As a result of immune system breakdown, HIV/AIDS patients are more susceptible to oral diseases, such as oral lesions that cause significant pain and oral infection leading to fevers, weight loss, and difficulty in eating, speaking, or taking medication. In fact, many of the first physical manifestations of HIV infection are found in the oral cavity. A dentist is often the first health care professional to diagnose these patients.

Private insurance and Medicaid coverage for dental services is very limited or simply unavailable for adults. This lack of adequate reimbursement particularly affects those dental education clinics that serve as the safety net for a significant number of Medicaid and HIV/AIDS individuals. The Ryan White HIV/AIDS Dental Reimbursement Program encourages treatment of patients by alleviating some of the financial burden incurred by the dental education institutions that serve them.

(4) $420 million to fund the National Institute for Dental and Craniofacial Research (NIDCR) in support of the American Association for Dental Research (AADR) funding level request

The National Institute for Dental and Craniofacial Research is deserving of enhanced federal funding. Past support has yielded significant results applicable not only to oral health, but to health in general. Through collaborative efforts with NIDCR, oral health researchers in U.S. dental schools have built a base of scientific and clinical knowledge that has been widely communicated and used to improve oral health. Research is advancing investigations in bone formation and craniofacial development, treatment of facial pain, salivary gland disorders, the link between periodontal diseases and pre-term low birth weight and arteriosclerosis, to name just a few.

The majority of dental, oral and craniofacial research is performed in the nation's dental schools. The dental schools are a national resource for the advancement through research of knowledge relevant to the NIDCR mission. As such, ADEA supports NIDCR's dental school initiative to develop and implement comprehensive institutional plans to improve research support infrastructure, to recruit research personnel, and to establish linkages to other research entities to, in turn, augment and expand their own research capacity.

A prime example of NIDCR-funded research at a U.S. dental school can be found at the University of Maryland where the dental school's research program is strong in neuroscience related to pain, mechanisms of bone growth and remodeling, dental disease, head and neck cancers, AIDS research, and dentistry's role in the event of a bioterror attack.

(5) $213 million to fund the National Health Service Corps (NHSC) in support of the President's funding level request

ADEA strongly supports the National Health Service Corps (NHSC) Scholarship and Loan Repayment Programs that assist students with the rising costs of financing their health professions education, while promoting primary care access to underserved areas. It is critical that the NHSC receive increased funding to meet the health needs in the national rural and underserved communities. With the passage of the Health Care Safety Net Amendments Act last session of Congress, ADEA and the NHSC have begun exploring ways in which we can increase participation in the Corps.

(6) $105 million for the Indian Health Service Dental Programs

The Indian Health Service Loan Repayment Program provides oral health care service to Native Americans and Alaska Natives focusing on the prevention and amelioration of oral health diseases. In exchange for full-time clinical practices at one of the 280 hospital sites located in 35 states, dentists receive up to $20,000 per year on their qualified student loans in addition to a salary (2000 salary range was $46,000–$82,000).

(7) $18 million to fund the Centers for Disease Control and Prevention (CDC) Oral Health Program in support of the American Dental Association's funding level request

The CDC Oral Health Program supports state and community-based programs and communicates with the public to prevent oral disease and reduce disparities in oral health. It works with states to establish surveillance systems that provide valuable health information to assess the effectiveness of programs and target them to populations at greatest risk.

CDC funding and expert assistance strengthens state oral disease prevention programs, allowing each state, territory or tribe to develop the vital public oral health infrastructure and capacity to be able to successfully support community based oral disease prevention programs.

(8) $20 million to fund the Dental Health Improvement Act, passed as part of the Health Care Safety Net Amendments of 2002 (Public Law 107–251)

A newly authorized program which now needs funding is the Dental Health Improvement Act, which will assist states in developing innovative dental workforce programs specific to their needs. Monies could be used for a variety of initiatives including: increasing access to oral health care for underserved populations, recruiting additional dental school faculty and practitioners in states, developing a prevention program which would include services such as water fluoridation, dental sealants, nutritional counseling, and establishing a state dental officer position or augmenting a current state dental office to coordinate oral health and access issues.

In conclusion, ADEA and its membership, thanks the Committee for the opportunity to present our views and budget requests for dental education and research programs in fiscal year 2004. Continuing the federal investment in these programs is vital. So too is the development of a partnership between the federal government and dental education programs to implement a national oral health plan that guarantees access to dental care for everyone, ensures continued dental health research, eliminates disparities, and eliminates workforce shortages.

PREPARED STATEMENT OF THE NATIONAL RURAL HEALTH ASSOCIATION

The National Rural Health Association (NRHA) thanks Chairman Specter, Ranking Member Harkin and members of the Subcommittee for the opportunity to submit this testimony for the record regarding fiscal year 2004 appropriations for programs important to our nation's rural health care delivery system. We believe we can offer you an insightful look at the unique health care needs of rural and frontier Americans.

The NRHA and its membership are grateful for the funding provided to rural health programs in fiscal year 2003 and the support shown for rural health by Congressional leaders. In fiscal year 2003 the Community Health Centers program, the National Health Service Corps, State Offices of Rural Health received increased funding. In addition, $5 million was added to the Rural Hospital Flexibility Grant Program to help small hospitals respond to the requirements of HIPAA, upgrade billing systems and implement quality improvement.

More than 62 million Americans live in rural and frontier areas. More than 8 million rural residents are uninsured and another 4.5 million are underinsured. The federal programs profiled below have a proven track record of expanding access to health care services in rural areas, thereby ensuring that the benefits of health care are available to all Americans, regardless of where they live.

The NRHA is a national nonprofit membership organization that provides leadership on rural health issues. The association's mission is to improve the health of rural Americans and to provide leadership on rural health issues through grassroots advocacy, communications, education and research. The membership of the NRHA is a diverse collection of individuals and organizations, all of whom share the common bond of an interest in rural health. Individual members come from all disciplines and include hospital and rural health clinic administrators, physicians, nurses, dentists, non-physician providers, health planners, researchers and edu-

cators, state offices of rural health and policy-makers. Organization and supporting members include hospitals, community and migrant health centers, state health departments and university programs.

One of the NRHA's top priorities is the National Health Service Corps program. The National Health Service Corps (NHSC) is a federal program aimed at encouraging health care professionals to practice in underserved rural and urban areas. Since 1972, more than 20,000 NHSC clinicians have fulfilled a pledge to serve rural and urban underserved communities in exchange for scholarships or loan repayment. Today more than 4.6 million people who would otherwise lack access to health care are served by over 2,400 NHSC professionals. 60 percent of these provide health care services to rural and frontier Americans. The NRHA believes that the National Health Service Corps deserves funding in fiscal year 2004 of $250 million to allow the program to provide access to health care to many more underserved rural and frontier communities.

State offices of rural health coordinate rural activities and interests across the state, provide information and technical assistance to rural communities and help to improve recruitment and retention of health professionals. State offices of rural health also serve as coordinators for national programs such as the Rural Hospital Flexibility Program and the State Children's Health Insurance Program. State offices of rural health are funded by a 3:1 state to federal match, with states providing three times the contribution of the federal government. The NRHA is appreciative of the increase in fiscal year 2003 to $8.5 million for State Offices of Rural Health, and supports $12 million in funding for fiscal year 2004.

The Consolidated Health Centers Program is comprised of four parts: Community Health Centers, Migrant Health Centers, Health Care for the Homeless Programs and Public Housing Primary Care Programs. Currently over 1,000 health centers serve more than 11 million patients. Community health centers are an important part of the rural safety net, providing care to the uninsured and underinsured who would otherwise lack access to health care, including 5.4 million rural residents (1 out of 10). Community health centers focus on wellness and prevention in addition to primary care services and foster community bonds through consumer boards governing each center. President Bush's five year Health Centers Initiative will add 1,200 new and expanded health center sites to raise the number of people served each year to 16 million by 2006. To adequately meet this goal and ensure new community health centers are added in rural areas, increased funding is necessary. The NRHA supports the expansion of the community health center program and advocates fiscal year 2004 funding of $1.769 billion.

The Rural Health Outreach and Network Development Grant Program serves to support innovative health care delivery systems as well as vertically integrated health care networks in rural America. Rural Health Outreach and Network Development Grants help establish new partnerships between health organizations and other community institutions to improve the delivery of clinical care and enable health care providers to be more efficient by sharing resources. According to data collected on the Rural Health Outreach program, about 80 percent of grantees have continued to provide services five years beyond their federal grant period. Since 1991, over 3.2 million people in almost every state have been served by the Outreach and Network Development Grant Program. The grants provide up to $200,000 a year for three years to each grantee.

The Huntingdon County Wellness Improvement Network and System Project is an Outreach grantee in Huntingdon, Pennsylvania. Huntingdon County is a rural community designated as a Health Professional Shortage Area (HPSA). The Project's goal is to develop and implement strategies to increase the number of health care professionals in the county; strengthen and integrate the health care and social service delivery systems; promote health, wellness, and disease-prevention to reduce risk and cost of chronic behaviorally-related diseases; improve the availability of clinical data to monitor outcomes; provide better quality and coordinated services; and support the expansion of services to meet community health needs. The grant supports a network membership which consists of the local hospital and several community-based agencies.

One Outreach grantee in rural Iowa is the Horn Memorial Hospital, in Ida Grove, Iowa, whose Timely Life Care (TLC) Project work to improve the quality of life for the chronically ill and provide caregiver support and education to the targeted population of persons 50 years and older. The TLC Project provides a palliative approach to patients whose disease is not responsive to curative treatment. The grant helps provide services that include home visits, respite, telemonitoring, education, counseling, pain management, and medication review. Community collaboration also plays a vital role in the program, with collaborators including a hospital, primary health care centers and rehabilitation centers.

The NRHA advocates $60 million in fiscal year 2004 for the Rural Health Outreach and Network Development Grant Program. Each year applications for this program greatly exceed funds available. Rural Health Policy Development (Research) funds health policy research focusing on the implications for rural Americans of decisions made by policymakers in Washington. The rural health research centers provide data on issues such as Medicare reimbursement, workforce and managed care in rural areas. The NRHA advocates $20 million in fiscal year 2004 for Rural Health Policy Development (Research). In adding special project earmarks to this line item, the NRHA strongly urges the Administration not to let the base funding for Rural Health Policy Development to fall below the fiscal year 2003 level of $9 million.

The Rural Hospital Flexibility Grant Program allows small, low-volume hospitals to convert to Critical Access Hospitals (CAHs), which provide needed emergency, outpatient and short-stay inpatient services. CAHs are encouraged to develop a network with other full-service hospitals in their region in order to provide a full range of needed services. It also helps communities to ensure that needed services, such as emergency medical services, will be available to their citizens. The Flex Program has been a lifeline to many communities, allowing them to keep their hospital open while networking different types of providers to ensure a continuum of care is available to rural residents. The NRHA advocates $50 million in fiscal year 2004 for the Rural Hospital Flexibility Grant Program.

The Small Hospital Improvement Program provides funds to help small hospitals respond to the requirements of HIPAA, upgrade billing systems and implement quality improvement. The NRHA advocates $50 million in funding for this program in fiscal year 2004.

The NRHA is very concerned about the shortage of health professionals in rural areas and supports health professions programs that train the future workforce for the rural health care infrastructure. Many health professions grant programs funded by the Department of Health and Human Services have a rural focus or component. Graduates of training programs with a rural component are more likely to practice in rural areas, therefore funding of these programs is critical to ensuring access to health care for rural residents.

Included in the Bureau of Health Professions (BHPr) are several programs that help to support the delivery of health care services in rural areas. The Primary Care Training cluster includes General Pediatrics, General Internal Medicine, Family Medicine, General Dentistry, Pediatric Dentistry, and Physician Assistants, provides for the education and training of primary care physicians, dentists, and physician assistants to improve access and quality of health care in underserved areas.

In the Interdisciplinary, Community-Based Linkages cluster of BHPr, the Area Health Education Centers have been a critical part of delivering the resources of academic health centers to students and clinicians in more remote rural and frontier areas. The Quentin N. Burdick Program for Rural Health Interdisciplinary Training facilitates collaboration between academic institutions and rural health care providers to improve the recruitment and retention of health professionals to serve rural areas.

The Public Health Workforce Development programs in BHPr are designed to increase the number of individuals trained in public health as well as to update the training of current public health professionals. Recent bioterrorism challenges and threats have highlighted the extent to which the public health infrastructure in the United States is uneven in its ability to respond to these challenges. Data compiled by the U.S. Department of Health and Human Services shows that less than half of the nation's public health agencies have the capacity to provide essential public health services. At this time when public health professionals are being asked to take on a critical role in surveillance and responding to bioterrorist attacks and threats, the public health workforce development deserves continued support by the federal government.

The Nursing Workforce Development programs provide training for basic and advanced degree nurses to improve the access to, and quality of, health care in underserved areas. Health care entities across the nation are experiencing a crisis in nurse staffing, caused in part by an aging workforce and lack of young people entering the profession. This crisis is felt more acutely in rural and frontier areas, which have a harder time recruiting staff and have trouble competing with the higher salaries and benefits offered in suburban areas. The Nursing Workforce Development programs are critical to making sure that health care professionals are available to provide services in underserved areas.

The NRHA is concerned that the President's proposed budget includes a drastic cut in funding for Health Professions programs and advocates funding of $940 mil-

lion (including $250 million for National Health Service Corps) in fiscal year 2004 for these programs.

Telehealth services address essential access to health care needs for rural Americans. These innovative programs currently provide medical care, technical assistance, distance learning and training programs to rural Americans in more than 30 states. The NRHA advocates $36 million for this program in fiscal year 2004. In adding special project earmarks to this line item, the NRHA strongly urges Congress not to let the base funding for Telehealth to fall below $6 million.

The Community Access Program (CAP) provides grants to health care providers to build integrated health care networks to serve uninsured and underinsured local residents. Because rural communities have a high rate of uninsured, CAP has been an essential program in various rural communities throughout the nation. The NRHA urges Congress to continue funding for this program, and advocates funding of $125 million in fiscal year 2004 for CAP.

The NRHA thanks Chairman Specter and the members of the subcommittee for the opportunity to submit testimony for the record on vital rural health programs supported by the federal government. We look forward to working with you as the annual appropriations process moves forward, and stand ready to help the Subcommittee and the Congress to ensure access to quality health care services for rural and frontier Americans.

PREPARED STATEMENT OF THE COALITION OF NORTHEASTERN GOVERNORS

The Coalition of Northeastern Governors (CONEG) is pleased to provide this testimony to the Senate Subcommittee on Labor, Health and Human Services, and Education regarding fiscal year 2004 appropriations for the Low Income Home Energy Assistance Program (LIHEAP). The Governors appreciate the Subcommittee's consistent support for the LIHEAP program, particularly the action to increase program funding this year. We also recognize the difficult decisions facing the Subcommittee this year. In light of sharply higher home energy prices and a lagging economy, we request the Subcommittee to provide $3 billion for LIHEAP in regular fiscal year 2004 funding and to provide advance appropriations for fiscal year 2005, with the authority to permit the release of emergency funds for unforeseen circumstances, such as price spikes in natural gas or heating oil, severe weather and other potential emergencies.

LIHEAP is a valuable tool in making home energy affordable for over 4 million of the nation's very low-income households—the elderly and disabled on fixed incomes and families with young children. Recent data shows that the percentage of income spent on home energy by these households can be four times higher than average households. For many of these households, annual income is simply not sufficient to pay high winter heating bills, even in periods of economic growth. Many low-income residents are forced to make dangerous choices between heating their homes or purchasing food or vital medications.

The recent rise in winter heating fuel prices has hit these vulnerable citizens especially hard. The Northeast is heavily dependent on deliverable home heating fuels such as home heating oil, kerosene, and propane. Price volatility in these fuels adversely affects the low-income households who, without the disposable income to purchase fuels off-season, typically enter the market when both the demand for and price of fuels are high.

This winter, sharp increases in the price of home heating fuels, increased joblessness and a lagging economy have created a heightened demand on the states' already-stretched LIHEAP programs. States across the country have seen significant increases in their regular caseloads as well as in requests for emergency assistance from those households in imminent danger of a fuel service cut-off. The projected need far outweighs the available funding, with only a fraction of eligible households nationwide—about 15 percent—being served at recent LIHEAP funding levels.

An increase in the regular LIHEAP appropriation to $3 billion for fiscal years 2004 and 2005 will enable states across the nation to reach more of those vulnerable citizens in need of assistance and more fully implement cost-effective measures to meet their continuing energy needs. Today, most winter heating programs have exhausted their program resources at the end of the heating season. As a result, they have limited ability to assist families who, in arrears on heating bills, face the prospect of having their home heating source cut off. In addition, without funds to carryforward to the new heating season, State LIHEAP programs lack the capability to undertake the "pre-buy" programs that help stabilize heating fuel prices for low-income households and expand the reach of limited program funds. An increased

federal appropriation, and advance funding, would allow states to manage the program resources in a manner to better take advantage of market opportunities.

Enactment of advance funding is vital to the states' program planning activities for the coming heating season. In the Northeast, where the heating season begins in early October, states generally spend up to 70 percent of the LIHEAP funds during the first two quarters of the fiscal year. Therefore, states must begin to plan and do program outreach in the spring and summer if they are to begin their LIHEAP program as soon as the new fiscal year starts. Advance funding helps ensure that states have the necessary funds to open their programs and provide timely assistance to low-income families who lack the financial resources to bear the initial costs of deliverable home heating fuels.

The current uncertainty of world energy markets underscores the importance of states being able to prepare for the potential of volatile energy prices. These preparedness activities, while critical, cannot fully shield our lowest-income citizens from the impacts of higher heating fuel prices. Your support for fiscal year 2004 LIHEAP appropriations at the $3 billion level and the enactment of advance fiscal year 2005 appropriations is urgently needed to enable our states to help mitigate the potential life-threatening emergencies and economic hardship that confront the region's most vulnerable citizens.

We thank the Subcommittee for this opportunity to share the views of the Coalition of Northeastern Governors, and we stand ready to provide you with any additional information on the importance of the Low Income Home Energy Assistance Program to the Northeast.

PREPARED STATEMENT OF THE SOCIETY OF THORACIC SURGEONS AND THE AMERICAN ASSOCIATION FOR THORACIC SURGERY

AHRQ RESEARCH IS ESSENTIAL TO CQI IN HEALTH CARE

The Society of Thoracic Surgeons and the American Association for Thoracic Surgery represent essentially all practicing cardiac and thoracic surgeons in the United States. We strongly support the extremely important work being done by the Agency for Healthcare Research and Quality (AHRQ) in determining best medical practices and in translating this knowledge to actual clinical implementation.

Important as is the research work of the NIH, we have learned from recent reports of the Institute of Medicine (most particularly the IOM's second study, Crossing the Quality Chasm) that major improvements are not only possible, but urgently needed, in the quality of care in the United States. This is not as simple as finding obvious "errors" in medical practice; progress in medical quality of care often depends on educational and other translational work that promotes the wide adoption of best practices.

Such translational work to extend the use of best medical practices is not the function of NIH; the responsibility falls to AHRQ. In the context of our country's commitment to medical research, AHRQ's funding at present is minimal and should be significantly increased.

We speak from first-hand experience. In 2001, AHRQ funded research and analysis of data in the existing risk-stratified data base on outcomes in Coronary Artery Bypass and Graft Surgery maintained by the Society of Thoracic Surgeons since 1989. The STS National Cardiac Database (STS NCD) is the largest voluntary clinical database in medicine with over 2.1 million patient records harvested since its inception. This AHRQ-funded analysis demonstrated that wider adoption of two practices—pre-operative use of beta blockers and, in older patients, use of the Internal Mammary Artery for at least one bypass (use of the IMA was already accepted as state of the art for younger patients) would significantly improve outcomes—that is, that adoption of these practices would save lives. These findings were published in the Journal of Thoracic and Cardiovascular Surgery and in JAMA in May 2002.

In addition, in 1999 AHRQ awarded the Society a $1.4 M grant award to scientifically validate the ability of a Medical Specialty Society to undertake CQI on a national scale. The STS implemented a national randomized clinical trial to determine if a low-intensity educational campaign would lead to faster adoption of these improved methods of patient treatment.

The AHRQ grant was the first national randomized trial in Quality Improvement in the surgical arena, with the potential to impact on overall CABG morbidity and

mortality nationwide.[1] Two regional STS organizations, in Iowa and Colorado, have been created as a result of this grant effort; importantly, both have created unique partnerships with CMS Quality Improvement Organizations in their respective states.

Results of the trial are positive, demonstrating that a multi-faceted, physician-led low-intensity effort can have an impact on the adoption of care processes into national practice. Adoption of these two practices has been significantly more rapid in the two states in which the educational QI effort was carried out than in the randomized control state. This successful CQI in CABG trial is a model for large-scale QI efforts across all disciplines of medicine.

Results from the trial were presented at the Late Breaking Clinical Trials session of the American Heart Association Scientific Sessions in November 2002. A manuscript based on the results of this trial has been submitted for possible publication in JAMA. Full funding of AHRQ is essential to the continuing improvement of medical practice through CQI projects similar to this groundbreaking work. Only AHRQ is carrying out research with this kind of immediate impact on patients' lives.

We ask that the Congress recognize the importance of the work being done by AHRQ through significant increases in its funding for fiscal year 2004. AHRQ programs in Continuous Quality Improvement (CQI) should be specifically

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PREPARED STATEMENT OF THE NATIONAL ASSOCIATION FOR STATE COMMUNITY SERVICES PROGRAMS

The National Association for State Community Services Programs (NASCSP) thanks this committee for its continued support of the Community Services Block Grant (CSBG), and seeks an appropriation of $650 million for the state grant portion of the CSBG, the same as its fiscal year 2003 appropriation. We are requesting flat funding this year in order to continue the efforts of the Community Services Network in assisting those families remaining on welfare with the intensive services they need to transition to work and to assist low-income workers in remaining at work through supportive services such as transportation and child care. These funds will also continue to assist states in developing services in the four percent of counties that are not currently served by the CSBG.

The fiscal year 2003 appropriation of CSBG included language regarding the use of the block grant at the state level. Many of the states have statues regarding the use of CSBG funds, which are state, legislated. Passing national legislation regarding the distribution of the block grant at the state level preempts the prerogative of states. NASCSP urges the committee to discourage the incorporation of authorization language in the appropriations act.

NASCSP is the national association that represents state administrators of the Community Services Block Grant (CSBG), and state directors of the Department of Energy's Low-Income Weatherization Assistance Program.

BACKGROUND

The states believe the Community Services Block Grant (CSBG) is a unique block grant that has successfully devolved decision making to the local level. Federally funded with oversight at the state level, the CSBG has maintained a local network of over 1,120 agencies which coordinate nearly $7.5 billion in federal, state, local and private resources each year. Operating in more than 96 percent of counties in the nation and serving nearly ten million low-income persons, local agencies, known as Community Action Agencies (CAAs), provide services based on the characteristics of poverty in their communities. For one town, this might mean providing job placement and retention services; for another, developing affordable housing; in rural areas it might mean providing access to health services or developing a rural transportation system.

Since its inception, the CSBG has shown how partnerships between states and local agencies benefit citizens in each state. We believe it should be looked to as a model of how the federal government can best promote self-sufficiency for low-income persons in a flexible, decentralized, non-bureaucratic and accountable way.

Long before the creation of the Temporary Assistance for Needy Families (TANF) block grant, the CSBG was setting the standard for private-public partnerships that

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[1] T. Bruce Ferguson Jr., Eric D. Peterson, Laura P. Coombs, Mary E. Eiken, Meghan Carey, Elizabeth R. DeLong, The Society of Thoracic Surgeons, Chicago, IL and the Duke Clinical Research Institute, Durham, NC. CQI in CABG: A National Randomized Trial in Quality Improvement Presented at the Late Breaking Clinical Trials session of the American Heart Association Scientific Sessions, November 19, 2002.

could work to the betterment of local communities and low-income residents. Family oriented, while promoting economic development and individual self-sufficiency, the CSBG relies on an existing and experienced community-based service delivery system of CAAs and other non-profit organizations to produce results for its clients.

MAJOR CHARACTERISTICS OF THE COMMUNITY SERVICES NETWORK

Leveraging capacity.—For every CSBG dollar they receive, CAAs leverage $4.46 in non-federal resources (state, local, and private) to coordinate efforts that improve the self-sufficiency of low-income persons and lead to the development of thriving communities.

Volunteer mobilization.—CAAs mobilize volunteers in large numbers. In fiscal year 2001, the most recent year for which data are available, the CAAs elicited more than 32 million hours of volunteer efforts, the equivalent of almost 15,000 full-time employees. Using just the minimum wage, these volunteer hours are valued at nearly $165 million.

Locally directed.—Tri-partite boards of directors guide CAAs. These boards consist of one-third elected officials, one-third low-income persons and one-third representatives from the private sector. The boards are responsible for establishing policy and approving business plans of the local agencies. Since these boards represent a cross-section of the local community, they guarantee that CAAs will be responsive to the needs of their community.

Adaptability.—CAAs provide a flexible local presence that governors have mobilized to deal with emerging poverty issues.

Emergency response.—CAAs are utilized by federal and state emergency personnel as a frontline resource to deal with emergency situations such as floods, hurricanes and economic downturns. They are also relied on by citizens in their community to deal with individual family hardships, such as house fires or other emergencies.

Accountable.—The federal Office of Community Services, state CSBG offices and CAAs have worked closely to develop a results-oriented management and accountability (ROMA) system. Through this system, individual agencies determine local priorities within six common national goals for CSBG and report on the outcomes that they achieved in their communities.

The statutory goal of the CSBG is to ameliorate the effects of poverty while at the same time working within the community to eliminate the causes of poverty. The primary goal of every CAA is self-sufficiency for its clients. Helping families become self-sufficient is a long-term process that requires multiple resources. This is why the partnership of federal, state, local and private enterprise has been so vital to the successes of the CAAs.

WHO DOES THE CSBG SERVE?

National data compiled by NASCSP show that the CSBG serves a broad segment of low-income persons, particularly those who are not being reached by other programs and are not being served by welfare programs. Based on the most recently reported data, from fiscal year 2000:

—70 percent have incomes at or below the poverty level; 47 percent have incomes below 75 percent of the poverty guidelines. In 2000, the poverty level for a family of three was $14,150.

—Only 49 percent of adults have a high school diploma or equivalency certificate.

—35 percent of all client families are "working poor" and have wages or unemployment benefits as income.

—17 percent depend on pensions and Social Security and are therefore poor, former workers.

—Fewer than 16 percent receive cash assistance from TANF.

—Nearly 60 percent of families assisted have children under 18 years of age.

WHAT DO LOCAL CSBG AGENCIES DO?

Since Community Action Agencies operate in rural areas as well as in urban areas, it is difficult to describe a typical Community Action Agency. However, one thing that is common to all is the goal of self-sufficiency for all of their clients. Reaching this goal may mean providing daycare for a struggling single mother as she completes her General Equivalency Diploma (GED) certificate, moves through a community college course and finally is on her own supporting her family without federal assistance. It may mean assisting a recovering substance abuser as he seeks employment. Many of the Community Action Agencies' clients are persons who are experiencing a one-time emergency. Others have lives of chaos brought about by many overlapping forces—a divorce, sudden death of a wage earner, illness, lack of a high school education, closing of a local factory or the loss of family farms.

CAAs provide access to a variety of opportunities for their clients. Although they are not identical, most will provide some if not all of the services listed below:

—employment and training programs
—transportation and child care for low-income workers
—individual development accounts
—micro business development help for low-income entrepreneurs
—a variety of crisis and emergency safety net services
—local community and economic development projects
—housing and weatherization services
—Head Start
—energy assistance programs
—nutrition programs
—family development programs
—senior services

CSBG funds many of these services directly. Even more importantly, CSBG is the core funding which holds together a local delivery system able to respond effectively and efficiently, without a lot of red tape, to the needs of individual low-income households as well as to broader community needs. Without the CSBG, local agencies would not have the capacity to work in their communities developing local funding, private donations and volunteer services and running programs of far greater size and value than the actual CSBG dollars they receive.

CAAs manage a host of other federal, state and local programs which makes it possible to provide a one-stop location for persons whose problems are usually multifaceted. Sixty percent (60) of the CAAs manage the Head Start program in their community. Using their unique position in the community, CAAs recruit additional volunteers, bring in local school department personnel, tap into religious groups for additional help, coordinate child care and bring needed health care services to Head Start centers. In many states they also manage the Low Income Home Energy Assistance Program (LIHEAP), raising additional funds from utilities for this vital program. CAAs may also administer the Weatherization Assistance Program and are able to mobilize funds for additional work on residences not directly related to energy savings that may keep a low-income elderly couple in their home. CAAs also coordinate the Weatherization Assistance Program with the Community Development Block Grant program to stretch federal dollars and provide a greater return for tax dollars invested. They also administer the Women, Infants and Children (WIC) nutrition program as well as job training programs, substance abuse programs, transportation programs, domestic violence and homeless shelters, as well as food pantries.

EXAMPLES OF CSBG AT WORK

Since 1994, CSBG has implemented Results-Oriented Management and Accountability practices whereby the effectiveness of programs is captured through the use of goals and outcomes measures. Below you will find the network's first nationally aggregated outcomes achieved by individuals, families and communities as a result of their participation in innovative CSBG programs during fiscal year 2001:

—70,360 participants gained employment with the help of community action (42 states reporting)
—17,426 participants retained employment for 90 days or more (24 states reporting)
—32,603 households experienced an increase in income from employment, tax benefits or child support secured with the assistance of community action (28 states reporting)
—12,662 families continued to move from homelessness to transitional housing (23 states reporting)
—33,795 families moved from substandard to safe, stable housing (26 states reporting)
—1,861 families achieved home ownership as a result of community action assistance (16 states reporting)
—22,903 participants achieved literacy or a GED (32 states reporting)
—12,846 participants achieved post secondary degree or vocational education certificate (22 states reporting)
—506,545 new service "opportunities" were created for low-income families as a result of community action work or advocacy, including affordable and expanded public and private transportation, medical care, child care and development, new community centers, youth programs, increased business opportunity, food, and retail shopping in low-income neighborhoods (28 states reporting)

All the above considered, NASCSP urges this committee to maintain funding the CSBG grant to the states at $650 million.

PREPARED STATEMENT OF THE AMERICAN HEART ASSOCIATION

Every 33 seconds another life is taken. Our parents, spouses, children and friends are all potential victims of a disease that is responsible for the deaths of nearly 40 percent of Americans. Heart disease, stroke and other cardiovascular diseases remain America's leading cause of death and a major cause of permanent disability.

The American Heart Association works to reduce disability and death from heart disease, stroke and other cardiovascular diseases. We commend this Committee for completing the doubling of the National Institutes of Health budget and for making funding for the Centers for Disease Control and Prevention a priority. But, we are concerned that our government is still not devoting sufficient resources for research and prevention to America's No. 1 killer—heart disease—and to our country's No. 3 killer—stroke.

STILL NUMBER ONE

Cardiovascular diseases represent a continuing crisis of epidemic proportions. Nearly 62 million Americans—1 in 5—suffer from one or more of these diseases, including men, women and children of all ages. More than half of those who suffer from cardiovascular diseases are under age 65. Hundreds of millions of Americans have major risk factors for these diseases—an estimated 50 million have high blood pressure, 42 million adults have elevated blood cholesterol (240 mg/dL or above), nearly 49 million adults smoke, more than 129 million adults are overweight or obese and nearly 11 million have proven diabetes. As the baby boomers age, the number of Americans afflicted by these often lethal and disabling diseases will increase substantially. Cardiovascular disease costs Americans more than any other disease—an estimated $352 billion in medical expenses and lost productivity in 2003. Heart disease is the major cause of premature, permanent disability of American workers, accounting for nearly 20 percent of Social Security disability payments. Heart defects are the most common birth defect and cause more infant deaths than any other birth defect. Stroke is a leading cause or permanent disability.

HOW YOU CAN MAKE A DIFFERENCE

Now is the time to capitalize on a century of progress in understanding heart disease, stroke and other cardiovascular diseases. According to a 1999 expert panel supported by this Committee, America's progress in reducing the death rate from cardiovascular disease has slowed, suggesting that new strategies against these killers are needed. The panel also reported that there are striking differences in cardiovascular disease death rates by race/ethnicity, socioeconomic status and geography. But promising, cost-effective breakthroughs in treatment and prevention are on the horizon. A continued, sustained investment in the NIH budget and appropriate funds for the NIH heart disease and stroke budget will support promising and critically needed new initiatives and the translation of that research into effective clinical and community programs. For fiscal year 2004, we urge you to:

—*Appropriate $30 billion (a 10 percent increase over fiscal year 2003 funding) for the NIH—to provide a continued, sustained investment in life-saving medical research*.—NIH research provides new treatment and prevention strategies, cuts health care costs, creates jobs and maintains America's status as the world leader in the biotechnology and pharmaceutical industries.

—*Provide $2.5 billion for NIH heart research and $348 million for NIH stroke research*.—Researchers are on the brink of advances to greatly enhance prevention and to provide new treatments so you and your loved ones can be spared the pain and suffering of heart disease and stroke.

—*Allot $75 million for the CDC's State Heart Disease and Stroke Prevention Program to elevate up to an additional 10 states from planning to program implementation and continue to support the other currently funded states*.—Science must be made applicable through community programs that encourage Americans to make healthful lifestyle choices to prevent and control heart disease and stroke.

—*Support $42.5 million to continue to help our communities buy automated external defibrillators (AEDs) and to train emergency and lay responders to use them*.—Rural Access to Emergency Devices Act is part of Public Law 106–505

and Community Access to Emergency Defibrillation Act is part of Public Law 107–188.

HEART AND STROKE RESEARCH BENEFITS ALL AMERICANS

Thanks to advances in addressing risk factors and in treating cardiovascular diseases, more Americans are surviving heart disease and stroke. Heart disease and stroke research and prevention breakthroughs are saving and improving lives. Several examples follow.

Stents.—Each year more than 1 million angioplasty procedures are performed to widen narrowed arteries to the heart and stents (wire mesh tubes used to prop open an artery) are now used in nearly 80 percent of angioplasty procedures. However, within six months, 20 to 40 percent of procedures must be repeated because the artery narrows again. The development of stents that can deliver drugs to prevent this renarrowing will significantly improve the subsequent course for many individuals.

Surgery to Reduce Risk for Stroke.—Often surgeons can prevent stroke by removing plaque buildup when one of the main arteries to the brain is severely narrowed. Research has defined the patients for whom this surgery is most helpful, as well as those for whom medical treatment is the better choice. An estimated 124,000 such procedures are performed each year.

State-of-the-Art Life-Extending Drugs.—Research has produced amazing new drugs to help prevent and treat heart disease and stroke. Drugs to control blood pressure and cholesterol are more effective than ever in saving lives and enhancing quality of life for millions of Americans. Some of these drugs can prevent heart attack and stroke. When prevention fails, primary angioplasty, opening the blocked artery to restore blood flow, and "clotbuster" drugs, such as tPA, can greatly reduce the size of heart attacks and the resulting disability. In stroke, the use of tPA, within 3 hours of the onset of symptoms, can restore blood flow and reduce chances of permanent disability by 33 percent, saving health care costs. These treatments offer hope for an estimated 1.1 million Americans who will suffer a heart attack and the more than 600,000 who will have a clot-based stroke this year.

Life-Saving Devices.—Defibrillators have been made small enough to be implanted and smart enough to read the heart's rhythm and restore a normal rhythm when needed. Recent research has suggested that many individuals at risk of sudden cardiac death after a heart attack can have their lives prolonged by these remarkable devices.

We commend Congress for fulfilling its historic commitment to double the NIH budget. We join other members of the research community in advocating for an fiscal year 2004 appropriation of $30 billion for the NIH to provide a continued, sustained investment in life-saving medical research and encourage continued investigation into new therapies. The NIH budget for heart diseases and stroke remains disproportionately under funded compared to the enormous burden these diseases place on our nation and the numerous promising scientific opportunities that could advance the fight against these disorders. Despite significant NIH budget increases and the fact that heart disease, stroke and other cardiovascular diseases meet the NIH's criteria for priority setting (public health needs, scientific quality research, scientific progress potential, portfolio diversification and adequate infrastructure support), NIH still invests only 8 percent of its budget on heart research and a mere 1 percent on stroke.

We have a particular interest in individual NIH components that relate directly to our mission. Our funding recommendations for these institutes follow.

HEART RESEARCH CHALLENGES AND OPPORTUNITIES FOR NHLBI

Significant advances have been made possible by more than 50 years of American Heart Association-sponsored research and more than a half-century of investment by Congress in the National Heart, Lung, and Blood Institute. However, while more Americans are surviving heart disease and stroke, these diseases can cause permanent disability, requiring costly medical care and loss of productivity and quality of life. Clearly more work is needed if we are to win the fight against heart disease and stroke.

Neither the NHLBI budget nor its heart and stroke-related budget kept pace with the campaign to double the NIH budget. We urge this Committee to appropriate funding for the NHLBI and for its heart disease and stroke-related budgets to support and expand current activities and to invest in promising and critically needed new initiatives to aggressively advance the fight against heart disease and stroke. To accomplish this goal, we advocate a fiscal year 2004 appropriation of $3.5 billion for the NHLBI, including $2.1 billion for heart disease and stroke-related budgets.

Several challenges and opportunities to advance the battle against heart disease are highlighted below.

Recovery of Heart Function with Circulatory Assist.—Nearly 5 million Americans live with the effects of heart failure, which kills more than 51,000 each year. Another 550,000 Americans will be diagnosed with this often-disabling condition this year. Because their damaged hearts cannot pump enough blood to meet their body's needs, victims often suffer fatigue and breathlessness. Fluid also builds up in other parts of their body, such as the ankles. The only treatment for sufferers of end-stage heart failure is a heart transplant. Since there is a severe shortage of hearts available for transplant, now mechanical circulatory assist devices are typically used to stabilize these patients until a suitable donor heart becomes available. With additional funding, a planned research program would capitalize on the amazing observation that the "rest" provided by mechanical assistance, in some cases, enables the heart to recover sufficiently to resume pumping blood on its own. Program goals include determination of whether sustained heart recovery is achievable through circulatory assist devices, characterization of patients who would likely benefit and study of other therapies that may improve outcomes.

Specialized Centers of Clinically Oriented Research (SCCOR) in Pediatric Heart Development.—Heart defects remain the most common birth defect and cause more infant deaths than any other birth defect. They cost an estimated $3 billion a year. About 2 million American adults and children live with the often-disabling consequences of heart defects existing at birth; and more than 4,300 die each year. An additional 40,000 babies will be born this year with heart defects; nearly 2,000 die before their first birthday. At least 35 types of such defects have been identified, ranging from simple defects to complex malformations. Ranging from existing at birth heart defects, disorders of heart function and heart rhythm, and acquired heart disease, pediatric heart disease is an important public health problem. With additional resources, a planned SCCOR program could enhance the prevention, diagnosis and treatment of these disorders by stimulating and fostering multidisciplinary clinical and basic research.

Pediatric Mechanical Circulatory Support Research and Development.—A recent NHLBI-supported study showed that circulatory assist devices, such as left ventricular assist devices, increased survival rates and quality of life for adult patients. But, such devices are not available for infants and children suffering from heart failure due to heart defects existing at birth and acquired heart disease. Additional resources are needed for planned research that would develop and evaluate pediatric circulatory assist devices. Such a device could provide short, intermediate or long-term lifesaving support for infants and children waiting for a heart transplant or development of new surgical or other therapies.

Diagnostic Screening Test for Salt Sensitivity.—About 50 million Americans have high blood pressure, the most critical stroke risk factor and a leading cause of heart attack and heart failure. The cause of 90 to 95 percent of high blood pressure cases is not known, but it is easily detected and usually controllable. Of those with high blood pressure, 32 percent are unaware they have it. Because excess dietary salt is a key risk factor for high blood pressure, public health officials caution all Americans to limit salt intake. Thus, the ability to identify those who are likely to benefit from salt restriction would provide strong incentives for susceptible people to heed the message. More resources would allow the NHLBI to begin planned development of a noninvasive or minimally invasive, rapid, practical diagnostic test for salt sensitivity, i.e., the propensity for an individual to experience an increase in blood pressure in response to a salt-rich diet. The NHLBI would involve the small business community in developing such a diagnostic test.

STROKE RESEARCH CHALLENGES AND OPPORTUNITIES FOR NINDS

A major cause of permanent disability and a key contributor to late-life dementia, stroke is America's No. 3 killer. Many of America's 4.7 million stroke survivors face debilitating physical and mental impairment, emotional distress and huge medical costs. About 1 of 4 stroke survivors is permanently disabled. An estimated 700,000 Americans will suffer a stroke this year; and nearly 170,000 will die. Considered a disease of the elderly, stroke also strikes newborns, children and young adults.

The NINDS stroke budget did not keep pace with the NIH doubling initiative. We urge you to provide sufficient funding for the NINDS to support and expand current activities and to invest in promising and critically needed new initiatives to aggressively prevent stroke, protect the brain during stroke and enhance rehabilitation. To accomplish this goal, we advocate an fiscal year 2004 appropriation of $1.8 billion for the NINDS, including $191 million for stroke. Some challenges and opportunities follow.

Strategic Stroke Research Plan.—As a result of report language provided by this Committee during the fiscal year 2001 appropriations process, the NINDS convened a Stroke Progress Review Group. This Group's report is serving as a blueprint for a long-range strategic plan on stroke research. They identified critical gaps in stroke knowledge and outlined five research priorities and seven resource priorities that would stimulate stroke research. Increased resources are needed to implement the first year of this plan.

Emerging Stroke Risk Factors.—More Americans are controlling major stroke risk factors, such as high blood pressure and smoking, yet the number of people falling victim to stroke continues to rise. Scientists are defining new stroke risk factors, re-examining existing ones and reconsidering the long-held belief that no difference exists in risk between young and older patients with similar risk factors. Researchers are studying heart valve disease, irregular heartbeats, the role of inflammation in clogging of arteries, and the long-term effects of previous high blood pressure. Increased funding to study these areas may lead to new ways to prevent stroke.

Therapeutic Strategies for Stroke.—Several major clinical trials have identified new methods for preventing and treating stroke in high-risk populations. However, with the increased number of strokes, and with the disparities evident in the treatment of stroke, new ways to prevent strokes, to raise awareness and to better treat strokes need to be developed and evaluated. Funding for new clinical studies is crucial for developing cutting-edge stroke treatment and prevention.

Stroke Education.—Less than 5 percent of patients eligible for tPA—the only FDA approved emergency treatment for clot-based stroke—receive it. As a member of the Brain Attack Coalition, organizations committed to fighting stroke, we work with the NINDS to increase public awareness of stroke symptoms and to call 9–1–1. Together, we launched a public education campaign, Know Stroke, Know the Signs. Act in Time, and we are striving to develop systems to make tPA readily available to appropriate patients. When these measures are implemented, stroke treatment will change from supportive care to early brain-saving intervention. More funding is needed to educate the public and health professionals about stroke.

RESEARCH IN OTHER NIH INSTITUTES BENEFIT HEART DISEASE & STROKE

Critical research seeking to prevent and find better treatments for heart disease, stroke and other cardiovascular diseases is supported by other NIH institutes and centers such as the National Institute on Aging, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Nursing Research and the National Center for Research Resources. It is important to provide sufficient additional resources for these entities to continue and expand their critical work.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

The lead health care quality agency, the AHRQ acts as a "science partner" with public and private health care sectors in improving health care quality, reducing health care costs and broadening access to essential services. The AHRQ is an active participant in developing evidence-based information needed by consumers, providers, health plans and policymakers to improve health care decision making. We join with the Friends of AHRQ in advocating an appropriation of $390 million for the AHRQ to improve health care quality, reduce medical errors and expand the availability of health outcomes information.

CENTERS FOR DISEASE CONTROL AND PREVENTION

Prevention is the best way to protect Americans' health and ease the huge financial burden of disease. Commitment cannot stop at the laboratory door. Resources must be made available to bring research to places where heart disease and stroke live—the towns and neighborhoods of America.

The CDC sets the pace on prevention. It builds a bridge between what we learn in the lab and how we live in communities. We advocate an fiscal year 2004 appropriation of $7.9 billion for the CDC, with a $350 million increase for state-based chronic disease prevention and health promotion programs.

Thanks to this Committee's support since fiscal year 1998, the CDC's State Heart Disease and Stroke Prevention Program covers 30 states, including the District of Columbia. But, only 8 states receive funding for program implementation. The other 22 states receive funding for program planning. This initiative allows states to design and/or implement programs to meet specific needs to prevent heart disease, stroke and other cardiovascular diseases. The CDC's 1997 report *Unrealized Prevention Opportunities: Reducing the Health and Economic Burden of Chronic Disease* states, "strong chronic disease prevention programs should be in place in every state to target leading causes of death and disability . . . and their risk factors." Since

cardiovascular diseases remain the No. 1 killer in every state, each state needs funding for basic implementation of a State Heart Disease and Stroke Prevention Program. With fiscal year 2003 funding, the CDC will add two states to the program and elevate, after a competitive process, two states from planning to program implementation. An fiscal year 2004 appropriation of $75 million for the State Heart Disease and Stroke Prevention Program would allow the CDC to elevate up to an additional 10 states from planning to program implementation and continue to support the other currently funded states.

The Paul Coverdell National Acute Stroke Registry is designed to track and improve delivery of care to stroke patients. The CDC is developing and testing prototypes for this registry in 8 sites in California, Georgia, Illinois, Massachusetts, Michigan, North Carolina, Ohio and Oregon. An appropriation of $5 million would allow the CDC to implement a statewide model registry and data-based intervention plans among three state health departments to enable them to monitor and improve stroke emergency transport response times, delivery of acute care and use of treatments to prevent recurrent stroke.

Also, we recommend the following fiscal year 2004 funding levels for the following CDC programs:

—$210 million for the Preventive Health and Health Services Block Grant;
—$65 million for the Nutrition, Physical Activity and Obesity Program;
—$83 million for the School Health Education Program; and
—$130 million for the Office of Smoking and Health to expand a national program to curb tobacco use.

Coupled with a nationwide comprehensive State Heart Disease and Stroke Prevention Program, these initiatives will help fight these diseases. Please make heart disease and stroke prevention a top priority.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

About 250,000 Americans die each year from sudden cardiac arrest. About 95 percent of the victims die before reaching a hospital. With each minute the heart beat is not restored to its normal rhythm, the victim's chance of survival drops about 10 percent. Within ten minutes, death is almost certain. Small, easy-to-use devices, AEDs can shock a heart back into normal rhythm and restore life. The Rural Access to Emergency Devices Act, part of Public Law 106–505, and the Community Access to Emergency Defibrillation Act, part of Public Law 107–188) authorizes funds to local first responders, school districts and other local government bodies to establish public access defibrillation programs. Cities and towns nationwide eagerly await funds from these important public health service grant awards, applying in droves for resources made available last year. An fiscal year 2004 appropriation of $42.5 million is required to support these authorized programs.

DEPARTMENT OF EDUCATION

Physical inactivity is a major risk factor for heart disease and stroke. Unfortunately, our nation's youth have fewer opportunities for physical education. Congress has appropriated significant funds for the Carol M. White Physical Education for Progress Act over the last two years. PEP provides critical funding for school-based physical education programs, which teach life-long physical activity habits and thereby prevents the onset of chronic disease, such as heart disease and stroke. We advocate a fiscal year 2004 appropriation of $100 million for PEP.

ACTION NEEDED

Increasing funding for research, prevention and treatment programs will allow continued strides in the battle against heart disease, stroke and other cardiovascular diseases. Our government's response to this challenge will help define the health and well being of Americans for decades to come.

PREPARED STATEMENT OF THE COMMUNITY MEDICAL CENTERS FRESNO, CA

Mr. Chairman and Members of the Subcommittee: My name is Dr. Philip Hinton and I am the Chief Executive Officer of Community Medical Centers in Fresno, California. Community Medical Centers is a not-for-profit, locally owned healthcare corporation that is committed to improving the health of the community. I am pleased to provide the subcommittee with a request for assistance in securing federal monies for a critical project in the Central San Joaquin Valley that would improve access to healthcare to the residents of Fresno County.

These are challenging times for those providing healthcare across the country. Recent events have highlighted the crisis that the healthcare system in this country is facing:

Recently, the week of March 10, 2003 was designated as national "Cover the Uninsured" week, publicizing the plight of over 41 million people across America lacking health insurance and resulting in the introduction of several initiatives in Congress to address the situation.

The recent introduction of S. 412, the Local Emergency Health Services Reimbursement Act of 2003, recognizing the need for the federal government to reimburse counties in southern and central California for emergency health care to undocumented residents.

Recent news articles reporting that emergency departments in hospitals across the country are overcrowded by uninsured and Medicaid populations. In the last 10 years, there has been an average increase in hospital emergency department visits by 33 percent while over 500 hospital emergency departments have closed. Due to a lack of health insurance, many are forced to resort to treatment at hospital emergency rooms rather than access primary care physicians.

It is clear that this crisis requires bold initiatives and leadership.

Community Medical Centers, located in Fresno, took over the County of Fresno's obligation for indigent healthcare in a 1996 landmark agreement. Since that time, Community has been providing inpatient and outpatient services to the residents of this community—regardless of their ability to pay. The availability of healthcare to all in Fresno County is a challenge at best. With a county boasting a population of 800,000, Fresno has some sobering statistics:

—An unemployment rate at 15 percent (almost three times the national average)
—Over 25 percent of the residents in the county living below the poverty line
—Over 30 percent of the residents in the county without health insurance (almost double the national average)
—The third highest asthma mortality rate in the nation
—The highest rates of teen pregnancy in the state
—The highest incidence of diabetes among the Hispanic population
—Late or no prenatal care for pregnant women
—Some of the lowest immunization rates in the nation (62 percent at age 2 versus 79 percent nationally)

These statistics point to the need to aggressively address the healthcare needs for the county in a comprehensive manner and offer an opportunity for Fresno County to serve as the perfect laboratory for such an experiment. Community has developed the concept of a primary healthcare network comprised of a local healthcare providers, Federally Qualified Health Centers, county health and human services agencies, schools and churches. A critical link to this network is the Community Caremobile, a doctor's office on wheels that travels to communities with no access to healthcare. The network will work to deliver both preventive and primary healthcare to the residents of Fresno County.

Key to this network is a hub known as the Ambulatory Care Center to be located on the campus of the Regional Medical Center in downtown Fresno. We are requesting $17.5 million in funding for the Ambulatory Care Center and have identified the following program for this $17.5 million request: the HHS Health, Resources and Services Administration (HRSA) Buildings and Facilities earmark in the fiscal year 2004 appropriations bill for Labor/HHS/Education. Because this program is specifically designated for buildings and facilities, we request your assistance in securing as much of the $17.5 million as possible through this program for the Ambulatory Care Center.

Although the challenges facing the healthcare community at the national level are significant, these challenges are magnified in the Central Valley beginning with the 30 percent of the residents of Fresno County lacking any form of health insurance. The result is the need to become creative and innovative in one's approach to providing health care. The concept of creating a hub, the Ambulatory Care Center in downtown Fresno, to be linked to a vast network of clinics and healthcare providers throughout the county is the only possible way to address the great need for accessible primary healthcare. By your providing significant funding for the Ambulatory Care Center, we can begin to address a severe crisis and improve the lives of many in Fresno County.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS

The National Association of Children's Hospitals (N.A.C.H.) is pleased to have the opportunity to submit the following statement for the hearing record in support of

the Children's Hospitals' Graduate Medical Education (CHGME) Payment Program in the Health Resources and Services Administration (HRSA).

On behalf of the nation's 60 independent children's teaching hospitals, we thank the Subcommittee for the remarkable achievement that Congress made last year in continuing to provide full, equitable GME funding for these hospitals, giving them a level of federal support for their teaching programs that is comparable to what all other teaching hospitals receive through Medicare. We urge the Subcommittee to continue to provide equitable funding for Children's Hospitals GME in fiscal year 2004 so that these institutions will have the resources to train and educate the nation's pediatric workforce.

N.A.C.H. is a not-for-profit trade association, representing more than 120 children's hospitals across the country. Its members include independent acute care children's hospitals, acute care children's hospitals organized within larger medical centers, and independent children's specialty and rehabilitation hospitals.

N.A.C.H. seeks to serve its member hospitals' ability to fulfill their four-fold missions of clinical care, education, research, and advocacy devoted to the health and well being of all of the children in their communities. Children's hospitals are regional and national centers of excellence for children with serious and complex conditions. They are centers of biomedical and health services research for children, and they serve as the major training centers for future pediatric researchers, as well as a significant number of our children's doctors. These institutions are major safety net providers, serving a disproportionate share of children of low-income families, and they are also advocates for the public health of all children.

BACKGROUND: THE NEED FOR CHILDREN'S HOSPITALS GME

While they account for less than 1 percent of all hospitals, the independent children's hospitals train nearly 30 percent of all pediatricians, half of all pediatric specialists, and a majority of future pediatric researchers. They also provide required pediatric rotations for many other residents. They train about 4,000 residents annually, and the need for these programs is even more heightened by the growing evidence of shortages of pediatric specialists around the country.

Prior to initial funding of the CHGME program for fiscal year 2000, these hospitals were facing enormous challenges to their ability to maintain their training programs. The increasingly price competitive medical marketplace was resulting in more and more payers not covering the costs of care, including the costs associated with teaching.

The independent children's hospitals were essentially left out of what had become the one major source of GME financing for other teaching hospitals—Medicare—because they see few if any Medicare patients. They received only ½00th (or less than 0.5 percent) of the federal support that all other teaching hospitals received under Medicare. This lack of GME financing, combined with the financial challenges stemming from their other missions, was threatening their teaching programs, as well as other important services.

In addition to their teaching missions, the independent children's hospitals are a significant part of the health care safety net for low-income children. On average, they devote nearly half of their patient care to children who are assisted by Medicaid or are uninsured. More than 40 percent of their care is for children assisted by Medicaid, and Medicaid covers only about 84 percent of the cost of that care. Without the Medicaid disproportionate share hospital (DSH) payments, Medicaid would cover only about 76 percent of children's hospitals' patient care costs. Further, these hospitals provide many important services from dental care to child abuse programs that are either uncovered or very underpaid.

The independent children's hospitals also are essential to the provision of care for seriously and chronically ill children in this country. They devote more than 75 percent of their care for children with one or more chronic or congenital conditions. They provide more than 40 percent to 75 percent of the inpatient care to children with many serious illnesses—from children with cancer or cerebral palsy, for example, to children needing heart surgery or organ transplants. In some regions, they are the only source of pediatric specialty care. The severity and complexity of illness and the services and resources that these institutions must maintain to assure access to this quality care for all children are also often inadequately reimbursed.

The CHGME program, and its relatively quick progress to full funding in fiscal year 2002, came at a critical time. Between 1997 and 2000, independent children's hospitals on average experienced declining operating margins and total margins. By fiscal year 2000 more than a quarter of the hospitals were not able to cover their operating costs with operating revenues, and nearly 20 percent were not able to

cover their total costs with total revenues. Thanks to the CHGME program, these hospitals have been able to maintain and strengthen their training programs.

Continuing this critical CHGME funding is more important for these hospitals than ever in light of serious state budget shortfalls in virtually every state in the country and the resulting pressures for significant reductions in state Medicaid programs. Further, unless Congress intervenes, cuts in the Medicaid DSH program that became law on October 1, 2002, plus additional federal cuts called for in the House-passed fiscal year 2004 Budget Resolution, will force states to make even more substantial reductions in their Medicaid programs with devastating results for children's hospitals and many other safety net hospitals in many states.

The pediatric community, including the American Academy of Pediatrics, Association of Medical School Pediatric Department Chairs, and others, has recognized the critical importance of the GME programs of the independent children's teaching hospitals, not only to the future of the individual hospitals and their essential services but also to the future of the nation's pediatric workforce and the provision of children's health care and advancements in pediatric medicine overall.

Lastly, many of the independent children's hospitals are a vital part of the emergency and critical care services in their communities and regions. They are part of the emergency response system that must be in place for bioterrorism other public health emergencies. Expenses associated with preparedness will add to their continuing costs in meeting children's needs

CONGRESSIONAL RESPONSE

In the absence of any movement towards broader GME financing reform, Congress in 1999 authorized the Children's Hospitals' GME discretionary grant program to address the existing inequity in GME financing for the independent children's hospitals and ensure that these institutions could receive equitable federal support to sustain their teaching programs. The legislation was reauthorized in 2000 through fiscal year 2005 and provided for $285 million through fiscal year 2001 and such sums as may be necessary in the years beyond.[1] Congress passed both the initial authorization (as part of the "Healthcare Research and Quality Act of 1999") and the reauthorization (as part of the "Children's Health Act of 2000").

With the support of this Subcommittee, Congress appropriated initial funding for the program in fiscal year 2000, before the enactment of its authorization. Following that enactment, Congress moved substantially toward full funding for the program in fiscal year 2001 and completed that goal, providing $285 million in fiscal year 2002 and $292 million in fiscal year 2003. This represents an extraordinary achievement for the future of children's health care as well as for the nation's independent children's teaching hospitals.

The $285 million appropriated in fiscal year 2002 was distributed at the end of the fiscal year through HRSA to 59 children's hospitals according to a formula based on the number and type of full-time equivalent (FTE) residents trained, in accordance with Medicare rules as well as the complexity of care and intensity of teaching the hospitals provide. Consistent with the authorizing legislation, HRSA has begun to allocate the $292 million appropriation—minus an across-the-board reduction of 0.65 percent million enacted as part of the omnibus fiscal year 2003 appropriations bill—in bi-weekly periodic payments to eligible independent children's hospitals.

FISCAL 2004 REQUEST

N.A.C.H. respectfully requests that the Subcommittee continue equitable GME funding for the independent children's hospitals by providing $305 million for the program in fiscal year 2004. This would continue the fiscal year 2002 appropriation of $285 million—the original full funding authorization level—and provide for an adjustment for inflation by the consumer price index to recognize higher wages and costs, building on the fiscal year 2003 appropriation of $292 million. The authorization, which provides for such sums as may be necessary in fiscal year 2002 and beyond, would allow for such an adjustment, and it would be in keeping with the provision of such adjustments in Medicare.

An fiscal year 2004 appropriation of $305 million for the federal Children's Hospitals GME Payment Program enjoys board support in the Senate. For example, on March 25, during debate on the Senate's fiscal year 2004 Budget Resolution, the Senate passed by voice vote S. Amdt. 354 to S. Con. Res. 23, a Sense of the Senate

[1] The Lewin Group, an independent health policy analysis firm calculated in 1998 that independent children's teaching hospitals should receive approximately $285 million in federal GME support for nearly 60 institutions to achieve parity with the financial compensation provided through Medicare for GME support to other teaching hospitals.

Resolution by Senator Michael DeWine that the Children's Hospitals GME should be funded at $305 million.

Adequate, equitable funding for CHGME is an ongoing need. Children's hospitals continue to train new pediatric residents and researchers every year. Children's hospitals have appreciated very much the congressional support they have received, including the attainment of the program's authorization in fiscal year 2002 and continuation of full funding with an inflation adjustment in fiscal year 2003. Now, N.A.C.H. asks Congress to maintain this progress in fiscal year 2004.

Support for a strong investment in GME at independent children's teaching hospitals is consistent with the repeated concern the Subcommittee has expressed for the health and well being of our nation's children—through education, health, and social welfare programs. It also is consistent with the Subcommittee's repeated emphasis on the importance of enhanced investment in the National Institutes of Health (NIH) overall, and in NIH support for pediatric research in particular, for which we are very grateful.

The CHGME funding has been essential to the ability of the independent children's hospitals to sustain their GME programs. At the same time, it has enabled them to do so without sacrificing support for other critically important services that also rely on hospital subsidy, such as many specialty and critical care services, child abuse prevention and treatment services, poison control centers, services to low-income children who have inadequate or no coverage, mental health and dental services, and community advocacy, such as immunization and motor vehicle safety campaigns.

In conclusion, the Children's Hospitals GME Payment Program is an invaluable investment in children's health. The future of the pediatric workforce and children's access to quality pediatric care, including specialty and critical care services, could not be assured without it. Again, N.A.C.H. thanks this Subcommittee and Congress for your continuing leadership and support.

For further information, please contact Peters D. Willson, vice president for public policy, N.A.C.H., at 703/797–6006 or pwillson@nachri.org.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The Centers for Disease Control and Prevention (CDC) is at the frontline of public health with a mission to prevent disease, illness, and injury. CDC works to ensure the well-being of Americans by detecting disease, providing accurate and timely information used in health decisions, and cooperating with partner groups likewise involved in health promotion. The recent release of the Institute of Medicine Report, "Microbial Threats to Health: Emergence, Detection, and Response," recognizes the "need for a new level of attention, dedication, and sustained resources to ensure the health and safety of this nation—and of the world." The $6.5 billion proposed for the CDC in fiscal year 2004 does not sufficiently address the complex health risks that confront the agency from within this country and throughout the world. Events just within the past month—possible bioterrorism against U.S. combat troops overseas and the emergence of yet another apparently new infectious threat—SARS (severe acute respiratory syndrome)—urgently underscore the need for increased funding for the CDC. The American Society for Microbiology (ASM) recommends that Congress appropriate $7.9 billion for CDC in fiscal year 2004, which is the recommendation of the CDC Coalition.

Fighting Infectious Diseases

The ASM is concerned about the adequacy of the proposed fiscal year 2004 funding of $332 million for CDC's infectious disease control program, which is a decrease of $3 million from fiscal year 2003. This level of funding is counter to the reality of infectious diseases, which continue to be the third leading cause of death in the United States and the cause of nearly one-third of deaths worldwide. Persistent complications such as antimicrobial resistance, newly identified pathogens like West Nile virus, newly emerging diseases such as SARS, and global human migration certainly are not evidence in support of decreased funding.

The CDC's complex and costly mission is to prevent the ravages of infectious disease here and around the world, whether familiar threats such as influenza or newly discovered, emerging diseases like SARS. Here and abroad, CDC personnel conduct surveillance, investigate epidemics, support both intramural and extramural laboratory research, and provide training and public education programs to many millions.

During the past decade, more than 35 new infectious diseases were identified; the current push to identify the source of SARS may add another emerging disease to

this deadly list. In response to the initial overseas SARS cases, the CDC activated its Emergency Operations Center to manage what is a complicated, international and multijurisdictional disease outbreak. The CDC also conducts intensive studies of other emerging diseases such as hantavirus; for instance, last year it provided funding to four academic institutions to study hantavirus transmission.

The CDC is expected to be at the forefront of any new infectious disease outbreak, providing epidemiological expertise and state-of-the-art laboratory assistance. The CDC recently established International Emerging Infections Programs in Thailand and Kenya and developed seven domestic and global sentinel surveillance networks to link health care providers facing these newly emerging diseases. Much of the fieldwork depends on the CDC's Epidemic Intelligence Service (EIS) Program. In fiscal year 2002, EIS officers participated in Epi-Aids missions to more than 70 outbreaks worldwide, at the request of local, state, and foreign health officials.

Old enemies also endanger America's public health, in spite of available prevention methods. In this country alone, an influenza pandemic would cause an estimated 89,000 to 207,000 deaths, 314,000 to 734,000 hospitalizations, and economic losses between $71 billion and $167 billion. Aware of this potential catastrophe, the CDC in the past year expanded U.S. sentinel surveillance sites for influenza. ASM recommends that an additional $10 million be allocated within the infectious diseases budget in fiscal year 2004, to prepare for a pandemic flu outbreak.

There have been great successes throughout years of immunization programs, forcing vaccine-preventable diseases to or near historically low incidences in the United States. Measles, for example, is no longer endemic and the CDC estimates that measles immunization saves this country both thousands of lives and $7 billion each year. Only two cases of rubella were reported to CDC in 2001, compared to 1,401 cases a decade ago. However, weaknesses persist in our immunization barricade against preventable infectious diseases. Nearly one million two-year-old Americans have not received one or more of the available recommended childhood vaccines. Vaccine-preventable diseases in adults is an even greater challenge: as many as 50,000 adults die each year of hepatitis B, influenza, and pneumococcal infections. The annual cost of these diseases exceeds $10 billion.

The fiscal year 2004 budget request includes more than $1.2 billion to continue CDC campaigns against HIV/AIDS, sexually transmitted diseases (STDs) and tuberculosis. This is more than $46 million above the President's fiscal year 2003 budget for these ongoing programs. Approximately 900,000 Americans are HIV-infected; unfortunately, the number of new HIV infections reported each year has been about 40,000 for the past decade, without showing any decline. STDs caused by chlamydia are the most commonly reported infectious disease in the United States (more than 700,000 cases in 2001). Non-HIV STDs cost the U.S. economy at least $10 billion in direct and indirect costs each year, due to an annual estimated 15 million new cases.

Prevention of disease is the CDC's primary mission—the ASM urges Congress to provide an additional $93 million in fiscal year 2004 to enable CDC to complete its strategic plan for the 21st century, "Preventing Emerging Infectious Diseases."

Global Infectious Disease

Disease outbreaks anywhere in the world put U.S. citizens at risk; American health has become intertwined with global health. In 2002, the CDC announced its Global Infectious Disease Strategy, to create effective collaborations with international partners against the emergence and spread of infectious diseases. International efforts can make impressive progress: the number of polio-endemic countries dropped from 125 in 1988 to only eight today. But if ignored, infectious disease anywhere could spread into disaster, as have periodic influenza outbreaks and HIV infection. The current SARS outbreak of just a few reported cases in China in November has increased to more than 1,600 worldwide, today. The suspected number of cases in the United States has grown to fifty-nine, across twenty-two states. CDC recognizes that protecting the well-being of Americans is now impossible without supporting global strategies. The Administration recognized this as well, in its recently announced International Mother and Child HIV Prevention Initiative, to be administered in part by the CDC and meant to reduce HIV transmission from infected mother to child by 40 percent. At the end of 2001, 2.7 million children younger than 15 were living with HIV/AIDS worldwide, nearly all of them infected by their mothers. The ASM recommends that Congress allocate $9 million over the appropriated fiscal year 2003 level, for global infectious disease activities.

Antimicrobial Resistance

Antimicrobial resistance among pathogenic microorganisms is a frightening trend found in a widening range of disease agents. The pathogenic agents of tuberculosis,

malaria and gonorrhea are among those that have developed mechanisms to disarm their standard drug treatments. A recent study at Harvard concluded that by the summer of 2004, as many as 40 percent of the strains of Streptococcus pneumoniae could be resistant to both penicillin and erythromycin. This streptococcus causes thousands of cases of ear infections, pneumonia, meningitis, and sinusitis every year. The CDC estimates that as many as 100,000 are hospitalized each year with methicillin-resistant Staphylococcus aureus infections, bacteria capable of causing many different illnesses including bloodstream and skin infections. In addition, antimicrobial-resistant tuberculosis bacteria, which have evolved new strains immune to drugs typically used to treat the disease, has also emerged. Government agencies joined the CDC in 2001 to address this trend under the Public Health Action Plan to Combat Antimicrobial Resistance. This past year, the CDC initiated a research grant program focused on antimicrobials in the environment and in rural areas and on ways in which resistant genes spread among pathogens. In recent weeks the agency launched a topic-specific education campaign for physicians, on using antimicrobials wisely and preventing the spread of resistant pathogens. The ASM recommends that an increase of $13 million be appropriated for antimicrobial resistance programs and activities implemented by the CDC.

Ensuring National Security and Public Health

As events in late 2001 sadly demonstrated, this nation and its citizens abroad are at high risk from possible terrorist attacks, including the intentional release of pathogenic microorganisms. The CDC responded immediately and aggressively to those events with personnel, information, and financial support. CDC requires adequate resources to optimally prepared to meet such tragedy, to join with state, local, and international agencies in a well-coordinated defense.

The proposed fiscal year 2004 budget for CDC includes $1.1 billion for the agency's multi-faceted Bioterrorism Preparedness and Response Program, equal to the fiscal year 2003 bioterrorism-related request. Within this sum are $940 million to improve state and local preparedness, $158 million to improve CDC's internal preparedness, and $18 million to continue anthrax research. This steady-state sum total reflects the creation of the new Department of Homeland Security and subsequent shift from CDC to the new department of the smallpox vaccine program and the Strategic National Stockpile (SNS) designed to warehouse counterterrorism vaccines and pharmaceuticals. Despite these two recent program shifts, the CDC responsibility for homeland security remains immense. The ASM supports the Administration's request of $940 million for state and local capacity. We also support and strongly encourage CDC efforts to quickly assess the cost of the smallpox immunization program, including an evaluation of the impact of the program on human resources and the redirection of resources from other state and local public health activities and broader bioterrorism preparedness, as recommended in a March 27 report by the Institute of Medicine's Committee on Smallpox Vaccination Program Implementation. The IOM recommendation was based on state and local health department concerns that resources are being diverted from other public health services to respond to smallpox preparedness and that cost issues constitute a difficulty in program implementation. The assessment should also focus on the human resources needed, training issues and the allocation of resources to state and local health departments. Understanding and responding to the cost implications is critical for the safe and effective implementation of the program and for funding of ongoing public health services and broader bioterrorism preparedness.

Following the attacks of September 11, 2001, and the intentional release of anthrax shortly thereafter, the CDC refocused its priorities to be ready against all types of terrorism, whether chemical, biological, radiological or conventional. In partnership with the Agency for Toxic Substances and Disease Registry (ATSDR), the CDC reinforced its capability to respond rapidly, having learned along with the nation that the public health system is central to any conflict with terrorism. The ongoing, integrated effort includes improving state and local laboratory capacity to detect possible biological and chemical agents, as well as upgrading surveillance and reporting systems nationwide.

Over the past year the CDC established a national Emergency Communication System, to quickly and accurately include all groups involved in defending public health. This system already has been utilized during the West Nile virus outbreak, the initial distribution of smallpox vaccine, and recently, to track the SARS outbreak. At the same time, the agency trained more than 1.5 million health professionals in terrorism-specific areas through its online Public Health Training Network. In 2002 the CDC released its National Public Health Performance Standards for state and local systems, part of its strategy to strengthen public health practice as called for by the 2002 Bioterrorism Act. This January, the CDC began distrib-

uting to state and local governments shipments of smallpox vaccine, which had been deposited by the agency at the centralized national vaccine stockpile. The CDC and ATSDR recently joined with the FBI in a renewed investigation of the 2001 anthrax contamination in Florida. CDC scientists have examined reputed anthrax-containing parcels/letters submitted by many state health departments.

What is learned about the epidemiology of infectious diseases in general also applies to potential weapons of bioterrorism, making all aspects of CDC infectious disease activities important to homeland security. Biological agents can be difficult to identify in advance of and even during an attack, and infectious disease can spread quickly through a population. The CDC is able to respond within minutes of receiving infectious outbreak reports, but strives to improve its own and others' counterterrorism capabilities. To upgrade its own responses, the CDC is revamping the Rapid Response and Advanced Technology (RRAT) laboratory at the agency's National Center for Infectious Diseases (NCID). NCID also is distributing millions of dollars to non-CDC investigators for basic research in biodefense and emerging infectious diseases, with emphasis on the A list of potential biological agents—those causing anthrax, botulism, plague, smallpox, tularemia, and viral hemorrhagic fevers, all easily disseminated and capable of high mortality rates. Through the government's Select Agent Program, the CDC and the Department of Agriculture register facilities that use these and other agents for legitimate purposes.

Reinforcing CDC Infrastructure

The total funding for CDC buildings and facilities in the fiscal year 2004 proposed budget is $114 million, which is $70 million less than the President's fiscal year 2003 request. CDC's priority items are security upgrades and construction of a new building for agency headquarters and the Emergency Operations Center. The CDC utilized last year's funding to open two new research laboratories, to investigate toxic chemicals in the environment and parasitic diseases, respectively. But the physical component of the CDC remains greatly inadequate, out-of-date and scattered. Some of CDC's laboratories continue to have leaking roofs, rotted floors, and cramped conditions.

Newly emerging diseases and today's greater risk of terrorism can overload an already strained communications system. The CDC tracks more than 60 notifiable infectious diseases in the United States, while watching worldwide for new and old diseases. Within the proposed fiscal year 2004 budget, CDC priorities include building a Public Health Information Network that goes beyond the many existing CDC surveillance systems. It will guarantee secure and accurate information-sharing in emergency and non-emergency situations. Last year the agency improved public access to its Internet information, increasing the average monthly visits to 3.6 million. It educated on-line thousands of health care providers about emerging critical issues such as smallpox and anthrax vaccines. The ASM recommends that Congress appropriate $250 million for the critical infrastructure needs at CDC.

PREPARED STATEMENT OF THE NATIONAL TREASURY EMPLOYEES UNION

Chairman Specter, Members of the Subcommittee: My name is Colleen M. Kelley and I am the National President of the National Treasury Employees Union (NTEU). NTEU represents more than 150,000 federal employees across 28 agencies and departments of the federal government, including employees in a number of agencies within the Department of Health and Human Services.

NTEU is proud to represent employees in the Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Administration for Children and Families (ACF), Administration on Aging (AoA), Office of the Secretary (OS), Office for Civil Rights (OCR), Program Support Center (PSC) and the National Center for Health Statistics (NCHS). NTEU also represents employees in the Social Security Administration's Office of Hearings and Appeals.

As you know, Mr. Chairman, for entirely too long now, most federal agencies and departments have been strapped for adequate funding. When federal agencies are denied the resources they need, services the American people expect and deserve are effectively denied. Front line federal employees feel this lack of resources directly and are frustrated by the continuing necessity of doing more with less.

The human capital crisis the federal government faces will only begin to turn around when we take the appropriate steps to treat our employees like assets to be valued instead of costs to be cut. Adequate and stable agency funding coupled with appropriate federal pay and benefits are the keys to ensuring that the government is able to attract and retain the federal employees it needs.

The need for the federal government to hire and maintain a highly trained and skilled workforce has never been more clear. Federal employees protect our Nation's medical supplies, they help secure our borders and they provide valuable information to their fellow citizens every day. They deserve to have the agencies they work for properly funded.

Unfortunately, this is often not the case. Agencies are frequently unable to provide appropriate training to their employees or even hire the necessary number of employees to accomplish their missions because of budgetary restrictions. The fiscal year 2004 budget request for agencies within the Department of Health and Human Services and the Social Security Administration is no different.

The Administration's fiscal year 2004 request for program management funding at the Health Resources and Services Administration (HRSA) is $157 million. Although this figure represents a $3 million increase in administrative funds over the fiscal year 2003 funding level, it is important to remember that HRSA's 2003 funding level represented a reduction of $2 million from the prior year. For an agency charged with insuring access to quality health care, especially to underserved populations—services that are in desperate need of expansion—a considerably larger increase in program management funding is called for. HRSA cannot effectively accomplish its mission without additional resources.

The President proposes a $1 million reduction in funding for the National Center for Health Statistics (NCHS) for fiscal year 2004, dropping the agency from its $126 million funding level in 2003 to $125 million. If this funding level were enacted, it would be the second year in a row that funding for the NCHS has been reduced. As you know, the work NCHS undertakes is critical to ensuring that national health care initiatives are effective and the agency deserves a more appropriate funding level.

The budget request for program management funds at the Substance Abuse and Mental Health Services Administration (SAMHSA) is $85 million, an increase of $8 million over the fiscal year 2003 funding level for this agency. SAMHSA is the federal agency charged with improving the quality and availability of treatment and intervention programs for those suffering from substance abuse and mental illness. NTEU is pleased to see this request, especially in light of the reduction in funding this agency suffered between fiscal year 2002 and 2003 when more than $14 million in program management funds were stripped from SAMHSA's budget. However, we are troubled by the proposal the President has made to reduce full time equivalent employment at the agency and contract out some current SAMHSA functions. NTEU strongly objects to this proposal and urges the Subcommittee to review this request carefully.

After static funding levels the past two years, the President's budget proposal for fiscal year 2004 for the Administration for Children and Families (ACF), represents an increase of $8 million for federal administration of the programs ACF oversees. Funding restrictions in past years have hampered this agency's ability to accomplish its missions and NTEU strongly supports increased funding for the federal administration of ACF programs.

However, at the same time, we must register our strong opposition to the budget's recommendation that the Head Start Program, administered extremely successfully by ACF for many years, be moved from the Department of Health and Human Services to the Department of Education. As the Chairman knows, Head Start is much more than a stand alone education program; it provides a comprehensive range of effective social services to low income families and at risk children. Proposals to transfer oversight of this premiere program risk destroying what most experts agree is one of the finest programs the federal government has ever operated. The founding principles of the program are as valid today as they were when the program was implemented almost 40 years ago.

Instead of proposing to move Head Start from the Department of Health and Human Services to Education, Congress should be focusing on providing the necessary resources to ensure that Head Start can serve more needy children and their families and be even more successful in the future. In NTEU's view, moving Head Start from HHS to Education is effectively a move to dismantle the program. While reading skills are an essential component of Head Start, they are by no means the only component. A child without enough to eat, a child suffering from abuse or depression or a child with difficulties in hearing or seeing is not a child likely to read well absent intervention. The program was placed under the Department of Health and Human Services in the first place because that agency was best equipped to help resolve the range of issues that may impact a child eligible for the Head Start program. That is no less true today.

Congress considered and soundly rejected a proposal to move Head Start out of the Department of Health and Human Services and into the Education Department

during the Carter Administration. The principles Congress adhered to at that time are equally true today and NTEU urges this Subcommittee's strong opposition to the proposal to move Head Start to the Department of Education.

The President's budget recommends no new funding for program administration for the Administration on Aging (AoA), instead opting to keep the agency's program administration funding level at $18 million for another year. With our country's rapidly growing older population, this is particularly troublesome. The AoA helps older Americans remain independent and productive and offers nutrition, caregiver support and preventive health programs. These are precisely the type of programs desperately in need of expansion, yet the fiscal year 2004 budget proposal, like the 2003 budget before it offer no new funding for these critical areas. The AoA funding level, too, requires the careful scrutiny of this Subcommittee.

The Office of the Secretary (OS) of the Department of Health and Human Services is also slated to receive no new funding in fiscal year 2004. Federal employees working in the Office of the Secretary help administer all of the programs operated by the Department of Health and Human Services. It is critical that this office be effectively funded and NTEU urges a significant funding increase for this division.

The President's budget recommends a small increase in program funding for the Office for Civil Rights (OCR). The recommendation would increase this agency's resources from their 2003 funding level of $33 million to $34 million in 2004. The HHS Office for Civil Rights helps to ensure that individuals have proper access to all the services and programs the Department offers. Moreover, this agency helps promote the privacy of medical information. In past years, OCR has been woefully underfunded and NTEU urges this body to carefully review their funding needs for 2004.

The Department of Health and Human Services' Program Support Center (PSC) offers a range of administrative services both to HHS agencies and other federal departments. The President's budget, which requests a $10 million increase in expenses for this key agency over their fiscal year 2003 funding level, deserves to be adopted by this body.

NTEU also represents employees in the Office of Hearing and Appeals (OHA) of the Social Security Administration. As the Chairman knows very well, OHA's mission is to assist those claimants who have been found ineligible for Social Security disability benefits by providing an impartial review and hearing on their cases. The growing backlog of cases before OHA prevents a fair and timely hearing for these individuals. One of the problems facing OHA is that it lacks sufficient decision makers to handle its rapidly growing workload.

For almost a decade, SSA's disability program has been in crisis. In 1995, SSA introduced a program called the Senior Attorney Program that was instrumental in reducing the backlog and improving processing times. In every respect, the Senior Attorney Program was a success. The agency's experienced staff attorneys were given the authority to decide and issue fully favorable decisions—without the time and expense of a full hearing—in those cases where the evidence clearly identified an individual as disabled. It materially improved both the quality and timeliness of service to the public. The OHA backlog fell from over 550,000 pending cases to a low of 311,000 at the end of fiscal year 1999.

Unfortunately, SSA chose to terminate this innovative program as it undertook its Hearings Process Improvement (HPI) plan, a plan SSA now admits was unsuccessful. The Senior Attorney Program benefited more than just those claimants who received their disability benefits sooner than would have otherwise been the case. Administrative Law Judge time was more wisely spent on cases that required a hearing, thereby reducing processing times for those cases as well.

NTEU urges the Committee to closely review the original Senior Attorney Program. Not only was it a huge success, it materially improved the quality of service to the public and resulted in administrative and program cost savings. With the inevitable increase in disability applications that is expected to occur as our population ages, the time to address the situation is now. The Senior Attorney Program worked. It did not consume additional resources, not did it require the hiring of new Administrative Law Judges. The Senior Attorney Program provides an answer with proven results and its termination was shortsighted. I hope this Subcommittee will carefully consider this as a potential solution to the growing backlogs facing the OHA.

Although the President's fiscal year 2004 budget for OHA would provide some additional funds to the agency, it appears to be little more than a down payment. The agency will continue to be unable to improve processing times for disability cases until it is provided with the appropriate resources for its mission. NTEU strongly urges both additional funding—and additional decision makers—for the Office of Hearings and Appeals.

Mr. Chairman, thank you very much for the opportunity to comment on the fiscal year 2004 budget proposal for agencies within the jurisdiction of your Subcommittee.

NATIONAL INSTITUTES OF HEALTH

PREPARED STATEMENT OF THE NATIONAL MPS SOCIETY, INC.

Mr. Chairman and members of the Subcommittee: My name is Les Sheaffer, I serve on the Board of Directors of the National MPS Society and as Chairman of the Committee on Federal Legislation. My 10 year old daughter Brittany suffers from MPS III. I am submitting this testimony for the purposes of expressing the views of the National MPS Society with respect to congressional appropriations for the National Institutes of Health in 2004 and biomedical research priorities and issues of importance to the MPS, ML and rare disease community.

I wish to offer my thanks to Chairman Specter and the members of the LHHS Subcommittee for their continuing support for enhanced investment in genetic and biomedical research, training and infrastructure at the National Institutes of Health.

There are 11 primary types of Mucopolysaccharidosis (MPS) and Mucolipidoses (ML) are genetic Lysosomal Storage Disorders caused by the body's inability to produce certain enzymes. Normally, the body uses these enzymes to break down and recycle dead cells. In affected individuals, the missing or insufficient enzyme prevents the normal breakdown and recycling of cells resulting in the storage of these deposits in virtually every cell of the body. As a result of the storage, cells do not perform properly and cause progressive damage throughout the body including the heart, bones, joints, respiratory system and central nervous system. While the disease may not be apparent at birth, signs and symptoms develop with age as more cells are damaged by the accumulation of deposits. The most unfortunate result of these disorders is childhood mortality in many cases.

MPS research has gained momentum in recent years, private sector investment, funding of research by non profit organizations, improved technology, increasing collaboration and the essential federal investment in valuable MPS and ML related research on the part of the National Institutes of Health have all contributed to a better understanding of these disorders. The recent (January 2003) recommendation by a FDA advisory committee to approve the enzyme replacement therapy product "Aldurazyme" is a testament to the continued progress in development of MPS and Lysosomal Storage Disorder (LSD) therapeutics and promise for future advancement.

The average MPS researcher obtains approximately 80 percent of the funding they utilize for MPS and ML research projects from the National Institutes of Health. These statistics are based upon the results of a poll of the Scientific Advisory Board of the National MPS Society in 2000. Clearly, strong federal funding of MPS related research is essential to ensure investigators have resources needed to perform critical research pursuing development of effective therapies for MPS and ML disorders.

The primary institutes supporting MPS related research include the National Institute of Diabetes Digestive and Kidney Diseases (NIDDK), National Institute of Neurological Disorders and Stroke (NINDS), National Heart Lung Blood Institute (NHLBI) and National Institute of Child Health and Human Development (NICHD), additionally resources for development and maintenance of LSD animal models is supported by the National Center for Research Resources (NCRR) and the Office of Rare Diseases (ORD) plays an important role in facilitating communication and coordination.

In September of 2002 the NINDS sponsored a scientific conference titled "Mucopolysaccharidosis—Therapeutic Avenues in the Central Nervous System" supported by NIDDK, NICHD and ORD. Bringing key investigators in the current MPS research community together with outside professionals in relevant fields of study contributed to greater interest in MPS related research and collaborative discussion on the critical issue of how we may treat the brain in MPS disorders.

We look forward to the growth and enhancement of NIH efforts to employ all available and appropriate mechanisms to support research that contributes to the development of therapeutic approaches for the CNS in Lysosomal Storage Disorders like MPS, ML and other deadly diseases that rob the quality of life and future of thousands of children every year. The progression of neurological damage in MPS disorders is profound and has yet to effectively treated or managed in any MPS or ML disorder.

As you know Requests for Applications (RFA) are a valuable tool for stimulating research in a targeted area. For example we are hopeful the now expired RFA soliciting proposals for Gene Therapy for Neurological Disorders (NS–02–007) will provide knowledge so valuable to better understanding how we may one day treat these multi systemic disorders. RFA's issued in 2003 supporting Rare Diseases Clinical Research (RR–03–008) and Drug Screening in Animal Models (NS–03–003) are promising and represent an enhancement to efforts to better serve the rare disease research community.

In this context we wish to express in the strongest possible way our support for the employment of a targeted funding mechanism with a focus on addressing Central Nervous System (CNS) issues. This intuitive with appropriate focus, particularly on the Blood Brain Barrier (BBB) as an impediment to treating Lysosomal Storage Disorders will in our view will present a meaningful contribution to filling the gaps in important current research and embark on the path that will lead to development of effective therapies for MPS and many other disorders.

In light of these facts it is clear that investment allowing the NIH to fulfill its mission to support intramural and extramural research is essential to ensuring current MPS and ML related research is supported and resources are available to take advantage of the promising research we expect to see continue to develop.

I have reviewed the Presidents proposed budget for the NIH for fiscal year 2004 and respectfully disagree with the approximate 2 percent increase in the NIH budget for fiscal year 2004. The Board of Directors and the membership of the National MPS Society I wish to express our support for a minimum increase in the budget of the National Institutes of Health budget of approximately 8 percent for fiscal year 2004. This funding level will ensure that current commitments are fully met and provide resources necessary to ensure the growth and enhancement of federally supported quality biomedical research, valuable research that will continue to solidify the position of the United States as the world leader in health research.

The Board of Directors and members of the National MPS Society fully recognize the many challenges we face as a nation with respect to maintaining of security and homeland defense as well as the significant demands placed on public resources required to support or military efforts to secure our national security and global interests. Like all Americans we have an interest in providing the resources needed to ensure our way of life.

The unique perspective provided in caring for a child with a serious and most often fatal disease grants a clear vision of multiple aspects of protecting our children, some are quite tangible including effective and affordable health care and related services for our children. When considering research, we steadfastly maintain the belief, founded in fact, that strong funding of the NIH remains essential to ensure the continued advancement of basic research science and understanding of thousands of diseases affecting society, diseases that like MPS and ML rob the quality of life, financial stability and ultimately the lives of millions of American children and adults.

In closing I wish to again thank the members of the Labor Health and Human Services Subcommittee for your continued dedication to medical research and the completion of the Congressional commitment to double the budget of the National Institutes of Health in 2003.

Please carefully consider the information presented here, it is our sincere hope that future budget and appropriations decisions continue to reflect the advancement of and investment in medical research as the highest possible priority for years to come. Our children and those of future generations deserve nothing less.

PREPARED STATEMENT OF THE AMERICAN THORACIC SOCIETY

SUMMARY OF FUNDING RECOMMENDATIONS

[In millions of dollars]

National Institutes of Health	30,000.00
National Heart, Lung, and Blood Institute	3,287.57
National Institute of Allergy and Infectious Disease	3,237.96
National Institute of Environmental Health Sciences	727.32
Fogarty International Center	72.93
National Institute of Nursing Research	153.67
Centers for Disease Control and Prevention	7,900.00
National Institute for Occupational Safety and Health	307.00
Office on Smoking and Health	130.00

Environmental Health: Asthma Activities	70.00
Tuberculosis Control Programs	528.00

The American Thoracic Society (ATS) is pleased to present its recommendations for programs in the Labor Health and Human Services and Education Appropriations Subcommittee purview. The American Thoracic Society, founded in 1905, is an independently incorporated, international education and scientific society which focuses on respiratory and critical care medicine. The Society's members help prevent and fight respiratory disease around the globe through research, education, patient care and advocacy. The Society's long-range goal is to decrease morbidity and mortality from disorders and life-threatening acute illnesses.

MAGNITUDE OF LUNG DISEASE

Each year, an estimated 344,500 Americans die of lung disease. Lung disease is America's number three killer, responsible for one in every seven deaths. More than 30 million Americans suffer from a chronic lung disease. In 2002, lung diseases cost the U.S. economy an estimated $144.9 billion in direct and indirect costs.

Lung diseases represent a spectrum of chronic and acute conditions that interfere with the lung's ability to extract oxygen from the atmosphere, protect against environmental or biological challenges and regulate a number of metabolic processes. Lung diseases include: chronic obstructive pulmonary diseases, lung cancer, tuberculosis, pneumonia, influenza, sleep disordered breathing, pediatric lung disorders, occupational lung disease, sarcoidosis and asthma.

The ATS is pleased that the Administration and Congress fulfilled its commitment to double the National Institute of Health (NIH) budget in fiscal year 2003. However, we are extremely concerned with the President's fiscal year 2004 budget that proposes a mere 2 percent increase for NIH. We thank the Senate for approving a 10 percent increase for NIH and hope that the final appropriations numbers will reflect the Senate number. In order to stem the devastating effects of lung disease, research funding must continue to grow to continue with the medical breakthroughs made over the past five years. While our statement will focus on selected parts of the Public Health Service, the American Thoracic Society is firmly committed to appropriate funding for all sectors of our nation's public health infrastructure.

COPD

Chronic Obstructive Pulmonary Disease, or COPD, is a growing health problem. Yet, it remains relatively unknown to most Americans and much of the research community. COPD is an umbrella term used to describe the airflow obstruction associated mainly with emphysema and chronic bronchitis. COPD is the fourth leading cause of death and disability in the United States and the third leading cause of death worldwide.

While the exact prevalence of COPD is not well defined, it affects tens of millions of Americans and can be an extremely debilitating condition. It has been estimated that 10 million patients have been diagnosed with some form of COPD and as many as 24 million more are undiagnosed.

In 2001, 13.3 million adults in the United States were estimated to have COPD. In addition, according to the new government data based on a 2001 prevalence survey, three million Americans have been diagnosed with emphysema and 11.2 million are diagnosed with chronic bronchitis. In 2000, 122,009 people in the United States died of COPD, with the death rate for women with COPD surpassing the death rate of men with COPD. COPD costs the U.S. economy an estimated $30.4 billion a year.

Medical treatments exist to address symptom relief and slow the progression of the disease. Today, COPD is treatable but not curable. Fortunately, promising research is on the horizon for COPD patients. Research in the genetic susceptibility underlying COPD is making progress. Also, there are promising research leads on medications that might be able to repair damage to lung tissue caused by COPD. Additional research is needed to pursue these leads.

Despite these promising research leads, the ATS feel that research resources committed to COPD are not commensurate with the impact COPD has on the United States and the world. The best approach to stem the growth of COPD is through prevention, education and more public awareness. The ATS strongly recommend that the NIH and other federal research programs commit additional resources to COPD research and educational programs.

ASTHMA

Asthma is a chronic lung disease in which the bronchial tubes of the lungs become swollen and narrowed, preventing air from getting into or out of the lung. A broad range of environmental triggers that vary from one asthma-sufferer to another causes these obstructive spasms of the bronchi.

Asthma is on the rise and is a serious public health concern. The following statistics tell of how devastating asthma is to our nation. It is estimated that 12 million people suffer from asthma, including over 4 million children. Rates are increasing for all ethnic groups and especially for African American and Hispanic children. While some children appear to out grow their asthma when they reach adulthood, 75 percent will require life-long treatment and monitoring of their condition.

Asthma is expensive. The growth in the prevalence of asthma will have a significant impact on our nation's health expenditures, especially Medicaid. The direct medical costs and indirect costs for asthma are estimated to exceed $14 billion annually. In fact, the value of reduced productivity due to loss of school days represented the largest single indirect cost at $1.4 billion and asthma represents the most common cause of school absenteeism due to chronic disease. In 2000, there were 9.3 million physician office visits, and 1.8 million emergency room visits due to asthma.

Asthma also kills. In 2000, 4,487 people in the United States died as a result of an asthma attack. Approximately, 65 percent of these deaths occurred in women. A disproportionate share of these deaths occurred in African American families.

Addressing the Growing Asthma Epidemic

As the prevalence of asthma has grown, so has asthma research. Researchers are developing better ways to treat and manage chronic asthma. Research supported by National Heart, Lung and Blood Institute (NHLBI) has discovered genetic components as well as how infectious disease contributes to asthma.

Basic research is also learning more about asthma. Researchers supported by NHLBI have developed better animal models to allow expression of selected asthmatic genetic traits. This will allow researchers to develop a greater understanding of how genes and environmental triggers influence asthma's onset, severity and long-term consequences.

The ATS also feels that Centers for Disease Control and Prevention (CDC) must play a leadership role in the ways to assist those with asthma. Currently, there are national statistical estimates that document that asthma is a growing problem in the United States. However, we do not have accurate data that provide regional and local information on the prevalence of asthma. To develop a targeted public health strategy to respond intelligently to asthma, we need locality-specific data. CDC should take the lead in collecting and analyzing this data.

Last year, Congress provided approximately $35 million for the CDC to conduct asthma programs. CDC will use these funds to conduct asthma outreach, education and tracking activities. The ATS recommends that CDC be provided $70 million in fiscal year 2004 to expand programs and establish grants to community organizations for screening, treatment, education and prevention of childhood asthma.

In the past, Congress enacted legislation that directs the National Asthma Education and Prevention Program at NHBLI to develop a plan for the federal government to respond to the growing asthma epidemic in the United States. This plan should bring together key public and private organizations to develop a national asthma plan to coordinate the many elements of an effective public health response to asthma. Components of a national plan should include research, surveillance, patient and provider education, community awareness, indoor and outdoor air quality, and access to health care providers and medication.

TUBERCULOSIS

Mr. Chairman, the first lung disease research began with the treatment of those who had tuberculosis or consumption, as it was called at the turn of the 20th century. Tuberculosis (TB) is an airborne infection caused by a bacterium, Mycobacterium tuberculosis. TB primarily affects the lungs but can also affect other parts of the body, such as the brain, kidneys or spine.

TB is spread through coughs, sneezes, and close proximity to someone with active tuberculosis. People with active tuberculosis are most likely to spread TB to others they spend a lot of time with, such as family members or coworkers. It cannot be spread by touch or sharing utensils used by an infected person.

There are an estimated 10 million to 15 million Americans who carry latent TB infection. Each has the potential to develop active TB in the future. About 10 per-

cent of these individuals will develop active TB disease at some point in their lives. In 2002, there were 15,678 cases of active TB reported in the United States.

The Institute of Medicine (IOM) recently published a report, entitled: "Ending Neglect: The Elimination of Tuberculosis in the United States." The report documents the cycles of attention and progress toward TB elimination, the periods of insufficient funding and the re-emergence of TB. The IOM report provides the United States with a road map of recommendations on how to eliminate TB in the United States. The IOM report identifies needed detection, treatment, prevention and research activities. The ATS have endorsed the IOM report and its recommendations.

The ATS is pleased to note that, for the time being, TB rates in the United States are declining. From a high in 1992 of 26,673 new cases, we have seen 10 straight years of decline. To help maintain control and accelerate the decline of TB in the United States, engage in the global effort to control tuberculosis, and develop new tools for the diagnosis, treatment and prevention of TB, the ATS recommends $528 million for the CDC to fund TB research in fiscal year 2004.

While declining overall TB rates is good news, the emergence and spread of multidrug resistant TB poses a significant threat to the public health of our nation. Continued support is needed if the United States is going to continue progress toward the elimination of TB.

The NIH also has a prominent role to play in the elimination of TB. Currently there is no highly effective vaccine to prevent TB transmission. However, the recent sequencing of the TB genome and other research advances has put the goal of an effective TB vaccine within reach. The National Institutes of Allergy and Infectious Disease have developed a Blueprint for Tuberculosis Vaccine Development. ATS encourages the subcommittee to fully fund the TB vaccine effort.

Fogarty International Center TB Training Programs

The Fogarty International Center (FIC) at NIH provides training grants to U.S. universities to teach AIDS treatment and research techniques to international physicians and researchers. The goal is to develop a cadre of health professionals in the developing world who can begin controlling the global AIDS epidemic.

Because of the link between AIDS and TB infection, FIC has created supplemental TB training grants for these institutions to train international health care professionals in the area of TB treatment and research. This supplemental program has been highly successful in beginning to create the human infrastructure to treat the nearly two billion people who have TB worldwide.

However, we believe TB training grants should not be offered exclusively to institutions that have received AIDS training grants. The TB grants program should be expanded and open to competition from all institutions. The ATS recommends Congress provide an additional $3 million for FIC to expand the TB training grant program from a supplemental grant to an open competition grant.

NIOSH—Researching and Preventing Occupational Lung Disease

The ATS is extremely concerned that the president's budget proposes to cut the National Institute of Occupational Safety and Health (NIOSH) extramural research program. The ATS strongly encourage this subcommittee to reject the Administration's proposed cut to the NIOSH research program. Occupational safety and health research are valuable and deserve additional funding.

Protecting the health of our nation's workforce will require research, training, tracking and new technologies. The ATS recommend that the subcommittee provide a $60 million increase for the NIOSH budget including $20 million for the NIOSH National Occupational Research Agenda (NORA). NORA represents a partnership research plan for occupational disease. The NORA agenda was developed with input from labor, business and the health community.

The ATS recommend an additional $20 million for NIOSH Emergency Preparedness agenda including activities at the National Personal Protective Technology Laboratory. In addition to improving workers safety, investments in protective technology will help our nation respond to the growing threat of bioterrorism. The ATS also recommend an additional $10 million for NIOSH-sponsored prevention, intervention and information programs. These programs respond to existing workplace health programs, conduct prevention education programs and work with labor and industry groups to lower the risk of workplace injury and illness.

A recent IOM Report, *Safe Work in the 21st Century: Education and Training Needs for the Next Decades Occupational Safety and Health Personnel*, identified a growing shortage of trained occupational health professionals in the United States. Unlike the majority of medical subspecialties, occupational health professionals do not receive Medicare training support. We recommend $10 million for Capacity Building for Worker safety and health including training opportunities for occupa-

tional health professionals at NIOSH-sponsored Centers of Excellence. The ATS believe more funds are needed to track the incidence of serious work-related illnesses and injury.

Physician Workforce Supply

The ATS is also concerned about the supply of physicians in the United States. A recent study published in the Journal of the American Medical Association predicts that there will be an acute shortage of physicians trained to treat patients with critical care illness and lung disease starting in 2007.[1] While the study focuses on supply of pulmonary/critical care physicians, what is driving the shortage is the predicated increase in demand for physician services caused by the aging of the U.S. population.

Policy makers have given much thought and attention to how the aging population will effect Social Security and other programs for the elderly. Significant attention has been given to the acute shortage of nurses. However, such forward thinking does not seem to be applied to our physician workforce.

We are pleased that Bureau of Workforce Analysis at HRSA will be conducting a study on physician workforce supply in the United States. The ATS is hopeful that HRSA study will confirm the looming shortage of physicians in United States and make policy recommendations on how best to add physicians to the workforce before it becomes a serious crisis.

LUNG-DISEASE OPPORTUNITIES AND ADVANCES

Pulmonary researchers have made significant advances in lung disease research. NHBLI has identified areas of lung disease research that they will be exploring in the next year. One area of focus will be with acute lung injury (ALI) and acute respiratory distress syndrome (ARDS). NHLBI created Specialized Centers of Clinically Oriented Research (SCCOR) in translational research in acute lung injury. Patients experiencing ALI and ARDS suddenly develop severe lung inflammation that results in hypoxemia, loss of lung compliance and possibly multi-organ system failure. The SCCOR program will foster multi-disciplinary basic and clinical research related to ALI and ARDS, which will eventually have a positive impact on their prevention, diagnosis and treatment.

Another area of focus is COPD and lung cancer research. As mentioned earlier, COPD is the fourth leading cause of death and disability in this country. Nearly a quarter of a million Americans die each year of either COPD or lung cancer. NHLBI hopes to address the gap in knowledge that a common pathogenetic mechanism may be involved as a risk factor for COPD and lung cancer. The research will focus on a search for the similarities of the cellular and molecular mechanisms that lead to COPD and lung cancer. This new research could have important implications for the prevention and management of both diseases.

In conclusion, lung disease is a growing problem in the United States. It is America's number three killer, responsible for one in seven deaths. The lung disease death rate continues to climb. Overall, lung disease and breathing problems constitute the number one killer of babies under the age of one year. Worldwide, tuberculosis kills three million people each year, more people than any other single infectious agent. The level of support this committee approves for lung disease programs should reflect the urgency illustrated by these numbers.

PREPARED STATEMENT OF THE CYSTIC FIBROSIS FOUNDATION

INTRODUCTION

On behalf of the Cystic Fibrosis Foundation, I am pleased to submit this statement to the Appropriations Subcommittee for Labor, Health and Human Services, and Education. The CF Foundation appreciates the opportunity to share with you the latest advances in cystic fibrosis (CF), and a recommendation for a strong federal role in the fight against this disease. The CF Foundation is committed to finding a cure and believes our efforts will be accelerated, with your support, by encouraging a more expansive partnership with the National Institutes of Health (NIH).

We are truly grateful for the leadership of this Subcommittee in doubling the appropriations for the NIH over the past five years. With the doubling of the budget complete, we urge the Subcommittee to maintain its diligence to ensure that the

[1] D. Angus, et al. Current and Project Workforce Requirements for Care of the Critically Ill and Patients with Pulmonary Disease: Can We Meet the Requirements of an Aging Population? JAMA 2000; 284:2762–2770.

NIH continues to flourish and that we reap the benefits of our world leadership in biomedical research.

Congress and the NIH have an opportunity now to impact CF research. We urge you and your colleagues to encourage the NIH to support the mission of the CF Foundation in its tremendous undertaking to translate basic research advances into new treatments. Because CF is an "orphan" disease, the role of the NIH in translating basic research into treatments is even more critical. The CF Foundation was pleased with the passage of The Rare Disease Act of 2002, as this new law focuses the NIH on supporting clinical trial networks for rare diseases. Recognizing the importance of clinical research in future treatments, the CF Foundation established a clinical trials program, the Therapeutics Development Network (TDN), in 1998. It includes strong patient protections and a centralized data management system. It has been acknowledged by NIH staff and others as a model for conducting clinical trials, especially for rare diseases.

To help move CF clinical research forward, we ask the Subcommittee to urge the NIH to partner with the CF Foundation to strengthen and expand the Therapeutics Development Network. We believe an expanded collaboration between the NIH and the CF TDN would have two clear benefits: (1) it would accelerate the pace of research on new CF treatments; and (2) it would provide valuable information to the NIH regarding the optimal structure of clinical trials networks for other rare genetic or metabolic diseases. By encouraging the NIH's support of CF research, this partnership offers Congress the opportunity to champion promising, mission-driven research.

We ask the Subcommittee to specifically recognize the National Center for Research Resources (NCRR) for its leadership in supporting innovative clinical trials networks to test new therapies and to accelerate the translation of basic research findings into new treatments. NCRR has fostered the development of networks, such as the TDN. To meet the growing opportunities for CF clinical trials, we urge the Subcommittee to encourage the NIH, through NCRR or the Office of Rare Diseases, to commit $5 million per year for the next five years to expand its support for clinical trials networks for new cystic fibrosis therapies. This contribution will allow additional clinical trials to be initiated and more therapies to be tested thereby meeting the urgent needs of people with CF for the development of new therapies.

CYSTIC FIBROSIS: THE DISEASE

We have come a long way in the battle against CF. When a child was diagnosed with CF in 1960, that child had a life expectancy of less than 10 years. Today, children who are diagnosed with CF have a predicted life expectancy of more than 30 years. Despite this tremendous progress, it is obviously not the cure we seek. Thirty years represents less than half of the average American lifespan. More must be done if we are to give all people with CF hope for a healthy future.

CF is a genetic disease that affects approximately 30,000 children and adults in the United States. An individual must inherit a defective copy of the CF gene from each parent to have the disease. CF causes the body to produce abnormally thick, sticky mucus, due to the faulty transport of sodium and chloride to the outer surfaces of the cells that line organs, such as the lungs and pancreas. Individuals with CF experience persistent coughing and wheezing and are particularly susceptible to chronic lung infections, including pneumonia. A bacterial or viral infection that minimally slows down a person without CF could be devastating and potentially life-threatening to someone with the disease. Individuals with CF also may have excessive appetite but poor weight gain because the pancreas is obstructed and digestive enzymes cannot reach the intestines.

Treatments for CF vary based on the severity of the disease. Most people with CF are treated by chest physical therapy, which requires vigorous percussion on the back and chest manually or with the use of mechanical devices to dislodge the thick mucus from the airways. Powerful antibiotics, which may be administered intravenously, orally, and by aerosol, may be used to treat lung infections to prevent life threatening lung damage. Individuals with CF cannot absorb enough nutrients; to maintain their health and avoid malnutrition, they need to eat an enriched diet and take both replacement vitamins and pancreatic enzymes. Eventually, lung transplantation may be necessary, which offers the few patients who successfully receive donated organs a new chance for a healthy future.

ADVANCES IN CF RESEARCH

With the fiftieth anniversary of the discovery of DNA by Watson and Crick upon us this month, we must pause to appreciate the knowledge and dedication of the scientists who opened the doors to genetic research. We continue to marvel at the

complexity of medical science and the elusiveness of unlocking the mysteries of genetic disease. With the discovery of the gene that causes CF in 1989 by scientists supported by the CF Foundation, there continues to be great optimism about new therapies that can result from this groundbreaking genetic research.

Just last year, researchers supported in part by the CF Foundation announced progress in applying gene therapy to CF. This latest application resulted in a fruitful but transient effect of the gene in the cells of patients with CF. We continue to believe in the promise of gene therapy and explore multiple avenues to develop this field of research.

Another advancement last year showed the effectiveness of azithromycin, a commonly prescribed antibiotic, in reducing inflammation in the airways, and improved lung function. This trial was conceived of and supported by the CF Foundation. It confirmed anecdotal reports that this drug might benefit the overall respiratory health of CF patients.

Despite these recent successes, the fate of compounds in the lab today, and the future of people with CF, lie in the hands—still—of the CF Foundation. With the economy flagging, more biotech companies find it difficult to raise venture capital funds. And those who are interested in CF are coming to the CF Foundation for financial assistance. Although they bring exciting research that promises to make a difference in this disease, many of these compounds—and many of these companies—will disappear in the current economic environment.

The CF Foundation is being asked to do more that it can possibly do to treat and cure this disease. It is difficult to say no to any project that might be "the one" that saves these individuals lives. However, it is not possible for the CF Foundation to take up the faltering reigns of the biotech industry alone. We must build a stronger partnership with the NIH if we are to save lives of people with CF today.

BENEFITS OF PARTNERSHIP TO NIH

Why should the NIH join forces with the CF Foundation? With our dedication to curing this disease, we have taken it upon ourselves to pursue promising research leads in rapid fashion and to support national standards of care to assist those with the disease. Many generous individual and corporate donors and successful special fund-raising events have joined our efforts. Supporters in the past few years include the Bill and Melinda Gates Foundation and Tom and Cydney Marsico. However, with the current state of the economy, and the uncertainty it brings to our continued fund-raising successes, we cannot achieve this goal alone. We believe a broader partnership with NIH will inure great benefits to both partners.

Founded in 1955 by parents who wanted to cure this disease in their children, the CF Foundation today supports a broad array of CF research and health care initiatives. These initiatives include:

—Accrediting and supporting more than 115 CF care centers at major teaching hospitals and community hospitals across the country. These care centers offer comprehensive diagnosis and treatment services to individuals with CF, improving the lives of patients with CF at these centers.

—Maintaining a national registry with data on patients with CF and their health status, a database that remains vitally important to ongoing efforts to improve the quality of health care for individuals with CF.

—Sponsoring a Therapeutics Development Program to pursue CF drug development, from the discovery of promising compounds through clinical evaluation. This program applies cutting-edge technologies to the screening of potential drug candidates, their evaluation in the laboratory, and their testing in pre-clinical studies and clinical trials, including large-scale studies involving patients with CF. In essence, a virtual pipeline for the development of drugs to treat CF is now underway.

—Funding grants to scientists to conduct CF research. The CF Foundation's awards include new investigator research grants, pilot and feasibility grants, clinical research grants, research fellowships, clinical fellowships, and student traineeships.

—Supporting 10 Research Development Program centers for basic research projects at leading universities and medical schools that focus on CF.

—Maintaining a centralized laboratory dedicated to identification of Burkholderia cepacia complex, a species of bacteria found in agricultural and consumer products that can be lethal to individuals with CF.

Exploring Clinical Research: The Therapeutics Development Network

All of the promising basic research advances in the nation cannot lead to new therapies without being tested in clinical trials. In 1998, the CF Foundation built an outstanding clinical trials program, the Therapeutics Development Network

(TDN), to conduct clinical trials to evaluate new therapies. The TDN provides access to top CF researchers to conduct trials, and to numerous patients who can enroll in trials. It plays a pivotal role in accelerating the development of new CF treatments to improve and save the lives of individuals with CF.

The clinical research within the TDN is focused on five types of treatment strategies: gene therapy, protein-assist therapies, chloride channel treatments, anti-inflammatory therapy, and anti-infection therapy. The comprehensive approach of the TDN is dictated by the fact that a cure for CF will probably be a combination of gene therapy, protein repair therapy, and drug or other therapies. Through the network, ten trials have been completed, and as many as ten more have been undertaken in recent months.

With the discovery of multiple drug compounds that must be tested before becoming new CF therapies, the CF Foundation has increased the number of medical institutions in the TDN. This past fall, we increased the network from eight centers to 14 around the country, which now includes centers at the University of Iowa and the Children's Hospital of Pittsburgh as well as ten other states. This expansion will help to speed up the examination of more potential therapies—speed that is essential to improve the health of these young people. They cannot wait half of their lifetime to obtain new treatments—which is the average time, 14 years, that it takes industry to develop a new drug. Furthermore, this speed does not compromise patient safety, because of the establishment of a data safety monitoring board, ethical advisors, patient safety committees, and other safeguards.

Today, the most significant challenge facing the CF Foundation is to ensure that we have the financial resources necessary for the expansion of the clinical trials network in order to pursue all the promising translational and clinical research opportunities before us.

An Opportunity for a Promising Partnership

The NIH has always made an incredible impact on our nation's basic research accomplishments. Now, it is important that the NIH join forces with the private nonprofit sector to take the next step to translate this basic research into treatments. With the interest of Congress, and the passion of the new NIH director, we feel great confidence that the NIH is making clinical research a priority. Many NIH institutes have clinical trials networks or collaborate with the private sector in undertaking clinical trials. These partnerships are making a difference in the lives of millions of Americans.

We request that the Subcommittee encourage the NIH to enter into a renewed partnership with the CF Foundation to support a rejuvenated CF clinical trials network. The Subcommittee has placed great faith in the biomedical research enterprise by providing significant boosts in NIH funding. We hope that the Subcommittee will now urge a robust public-private partnership in CF clinical trials to promote the goal of all basic research findings—helping patients to overcome disease and live longer, healthier lives. By working together, we can continue adding tomorrows every day.

Thank you again for the opportunity to submit this statement. The CF Foundation looks forward to working with Congress in continuing to support this biomedical research enterprise—one of the remarkable assets of this great nation.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR GERIATRIC PSYCHIATRY

The American Association for Geriatric Psychiatry (AAGP) appreciates this opportunity to present its recommendations on issues related to fiscal year 2004 appropriations for mental health research and services. AAGP is a professional membership organization dedicated to promoting the mental health and well being of older Americans and improving the care of those with late-life mental disorders. AAGP's membership consists of approximately 2,000 geriatric psychiatrists as well as other health professionals who focus on the mental health problems faced by senior citizens.

AAGP would like to thank the Subcommittee for its continued strong support for increased funding for the National Institutes of Health (NIH) over the last several years, particularly the additional funding you have provided for the National Institute of Mental Health (NIMH), the National Institute on Aging (NIA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the Center for Mental Health Services (CMHS) within the Substance Abuse and Mental Health Services Administration (SAMHSA). Although we generally agree with others in the mental health community about the importance of sustained and adequate Federal funding

for mental health research and treatment, AAGP brings a unique perspective to these issues because of the elderly patient population served by our members.

There are serious concerns, shared by AAGP and researchers, clinicians, and consumers that there exists a critical disparity between appropriations for research, training, and health services and the projected mental health needs of older Americans. This disparity is evident in the convergence of several key factors:

—demographic projections inform us that, with the aging of the U.S. population, there will be an unprecedented increase in the burden of mental illness among aging persons, especially among the baby boom generation;

—this growth in the proportion of older adults and the prevalence of mental illness is expected to have a major direct and indirect impact on general health service use and costs;

—despite the fact that effective treatment exists, the current mental health needs of many older adults remain unmet;

—the number of physicians being trained in geriatric mental health research and clinical care is insufficient to meet current needs, and this workforce shortfall is projected to become a crisis as the U.S. population ages over the next decade;

—a major gap exists between research, mental health care policy, and service delivery; and

—despite recent significant increases in appropriations for support of research in mental health, the allocation of NIMH and CMHS funds for research that focuses specifically on aging and mental health is disproportionately low, and woefully inadequate to deal with the impending crisis of mental health in older Americans.

Demographic Projections and the Mental Disorders of Aging

With the baby boom generation nearing retirement, the number of older Americans with mental disorders is certain to increase in the future. By the year 2010, there will be approximately 40 million people in the United States over the age of 65. Over 20 percent of those people will experience mental health problems. A national crisis in geriatric mental health care is emerging and has received recent attention in the medical literature. Action must be taken now to avert serious problems in the near future. While many different types of mental and behavioral disorders can occur late in life, they are not an inevitable part of the aging process, and continued research holds the promise of improving the mental health and quality of life for older Americans.

The current number of health care practitioners, including physicians, who have training in geriatrics is inadequate. As the population ages, the number of older Americans experiencing mental problems will almost certainly increase. Since geriatric specialists are already in short supply, these demographic trends portend an intensifying shortage in the future. There must be a substantial public and private sector investment in geriatric education and training, with attention given to the importance of geriatric mental health needs. We will never have, nor will we need, a geriatric specialist for every older adult. However, without mainstreaming geriatrics into every aspect of medical school education and residency training, broad-based competence in geriatrics will never be achieved. There must be adequate funding to provide incentives to increase the number of academic geriatricians to train health professionals from a variety of disciplines, including geriatric medicine and geriatric psychiatry.

Current and projected economic costs of mental disorders alone are staggering. The direct medical expense to care for a patient with Alzheimer's disease ranges from $18,000 to $36,000 a year per patient, depending on the severity of the disease. In addition, there are substantial indirect costs associated with caring for an Alzheimer's disease patient including social support, care giving, and often nursing home care. It is estimated that total costs associated with the care of patients with Alzheimer's disease is over $100 billion per year in the United States. Psychiatric symptoms (including depression, agitation, and psychotic symptoms) affect 30 to 40 percent of people with Alzheimer's and are associated with increased hospitalization, nursing home placement, and family burden. These psychiatric symptoms, associated with Alzheimer's disease, can increase the cost of treating these patients by more than 20 percent. Although NIA has supported extensive research on the cause and treatment of Alzheimer's, treatment of these behavioral and psychiatric symptoms has been neglected and should be supported through NIMH.

Depression is another example of a common problem among older persons. Of the approximately 32 million Americans who have attained age 65, about five million suffer from depression, resulting in increased disability, general health care utilization, and increased risk of suicide. Older adults have the highest rate of suicide rate compared to any other age group. Approximately 30 percent of older persons in pri-

mary care settings have significant symptoms of depression; and depression is associated with greater health care costs, poorer health outcomes, and increased mortality.

The enormous and widely underestimated costs of late-life mental disorders justify major new investments. The personal and societal costs of mental illness and addictive disorders are high, but advances in research and treatment will help save lives, strengthen families, and save taxpayer dollars.

The Benefits of Research on Public Health

The U.S. Surgeon General's Report on Mental Health (1999) and the Administration on Aging Report on Older Adults and Mental Health (2001) underscore the prevalence of mental disorders in older persons and provide evidence that research has lead to the development of effective treatments. These reports summarize research findings showing that treatments are effective in relieving symptoms, improving functioning, and enhancing quality of life. Preliminary findings suggest that these interventions reduce the need for expensive and intensive acute and long-term services. However, it is also well demonstrated that there is a pronounced gap between research findings on the most effective treatment interventions and implementation by health care providers. This gap can be as long as 15 to 20 years. These reports stress the need for translational and health services research focused on identifying the most cost-effective interventions, as well as creating effective methods for improving the quality of health care practice in usual care settings. A major priority (neglected to date) is the development of a health services research agenda that examines the effectiveness and costs of proven models of mental health service delivery for older persons.

Special attention also needs to be paid to inadequately or poorly studied, serious late-life mental disorders. Illnesses such as schizophrenia, anxiety disorders, alcohol dependence and personality disorders have been largely ignored by both the research community and the funding agencies, despite the fact that these conditions take a major toll on patients, their care givers, and society at large. Many of AAGP's members are at the forefront of groundbreaking research on Alzheimer's disease, depression, and psychosis among the elderly, and we strongly believe that more research funds must be focused in these areas. Improving the treatment of late-life mental health problems will benefit not only the elderly, but also their children, whose lives are often profoundly affected by their parents' illness.

While the funding increases supported by this Subcommittee in recent years have been essential first steps to a better future, a committed and sustained investment in research is necessary to allow continuous progress on the many research advances made to date.

National Institute of Mental Health

Fiscal year 2003 marked the end of the five-year, bipartisan effort in Congress to double the NIH budget. In his fiscal year 2004 budget, the President proposed an increase of $498 million over fiscal year 2003, which would bring the entire NIH budget to a level of $27.7 billion. This 1.8 percent increase pales in comparison with previous double-digit annual increases. A decline in budget increases could have a devastating impact on the ability of NIMH, and NIH as a whole, to sustain the ongoing, multi-year research grants that have been initiated over the last two to three years.

For NIMH, the President is proposing $1.382 billion for scientific and clinical research, an increase over the agency's fiscal year 2003 appropriation of $1.349 billion. It is important to note that from fiscal year 1999 through fiscal year 2003, NIMH received increases that lagged behind the increases of other institutes. The 8.4 percent increase that NIMH received for fiscal year 2003 was far below the average 12 to 13 percent increases received by other institutes from fiscal year 1999 through fiscal year 2002. This fall-off for fiscal year 2003 is the result of disproportionately large increases for bio-terrorism research at the National Institute for Allergy and Infectious Diseases and a reallocation of funds from across NIH to the Centers for Disease Control. As Congress moves forward with deliberations on the fiscal year 2004 budget, AAGP believes that NIMH should receive a percentage increase that, at the very minimum, is at least equal to the average percent increase for the other NIH institutes.

Commendable as recent funding increases for NIH and NIMH have been, AAGP would like to call the Subcommittee's attention to the fact that these increases have not always translated into comparable increases in funding that specifically address problems of older adults. Data supplied to AAGP by NIMH indicates that while extramural research grants by NIMH increased 59 percent during the five-year period from fiscal year 1995 through fiscal year 2000 (from $485,140,000 in fiscal year 1995

to $771,765,000 in fiscal year 2000), NIMH grants for aging research increased at less than half that rate: only 27.2 percent during the same period (from $46,989,000 to $59,771,000).

AAGP is pleased that in recent months NIMH has renewed its emphasis on mental disorders among the elderly, and commends the creation of an intra-NIMH consortium of scientists concerned with mental disorders in the aging population. However, funding for aging mental health research is still not keeping pace with that of other adult mental health research, and is actually decreasing proportionally when considered in the context of anticipated projections in growth of mental disorders in older persons. For example, the proportion of total NIMH newly funded extramural research grant funding devoted to aging research declined from an average of eight percent from fiscal years 1995 to 1999 to a low of six percent in fiscal year 2000. To reverse this trend, it will also be important to constitute grant review committees with specialized expertise in geriatrics to ensure fair review of research proposals. Review committees must take into account knowledge of the unique biological factors associated with the aging brain, the high prevalence of co-occurring medical illnesses, and the specific systems for financing and health services delivery for older Americans.

In addition to supporting research activities at the NIMH, AAGP supports increased funding for research related to geriatric mental health at the other institutes of the NIH that address issues relevant to mental health and aging, including the National Institute of Aging (NIA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the National Institute of Neurological Disorders and Stroke.

Center for Mental Health Services

It is also critical that there be adequate funding increases for the mental health initiatives under the jurisdiction of the CMHS within SAMHSA. While research is of critical importance to a better future, the patients of today must also receive appropriate treatment for their mental health problems. SAMHSA provides funding to State and local mental health departments, which in turn provide community-based mental health services to Americans of all ages, without regard to the ability to pay. AAGP was pleased that the final budgets for both fiscal year 2002 and fiscal year 2003 included $5 million for evidence-based mental health outreach and treatment to the elderly. AAGP worked with members of this Subcommittee and its House counterpart on this initiative, which is a very important first step in addressing the mental health needs of the nation's senior citizens.

Funding for the dissemination and implementation of evidence-based practices in "real world" care settings must be a top priority for Congress. Despite significant advances in research on the causes and treatment of mental disorders in older persons, there is a major gap between these research advances and clinical practice in usual care settings. The greatest challenge for the future of mental health care for older Americans is to bridge this gap between scientific knowledge and clinical practice in the community, and to translate research into patient care. Adequate funding for this geriatric mental health services initiative is essential to disseminate and implement evidence-based practices in routine clinical settings across the states. Consequently, we would urge that the $5 million for mental health outreach and treatment for the elderly included in the CMHS budget for fiscal year 2003 be increased to $20 million for fiscal year 2004.

Of that $20 million appropriation, AAGP believes that $10 million should be allocated to a National Evidence-Based Practices Program, which will disseminate and implement evidence-based mental health practices for older persons in usual care settings in the community. This program will be a collaborative effort, actively involving family members, consumers, mental health practitioners, experts, professional organizations, academics, and mental health administrators. With $10 million dedicated to a program to disseminate and implement evidence-based practice in geriatric mental health, there will be an assured focus on facilitating accurate, broad-based sustainable implementation of proven effective treatments, with an emphasis on practice change and consumer outcomes. Such a program should include several development phases including identification of a core set of evidence-based practices, development of evidence-based implementation, and practice improvement toolkits and field-testing of evidence-based implementation. This program will provide the foundation for a longer-term national effort that will have a direct effect on the well-being and mental health of older Americans.

Agency for Healthcare Research and Quality

One of the most valuable resources in our efforts to improve access to and the quality of geriatric mental health services is the Agency for Healthcare Research

and Quality (AHRQ). In recent years the Agency has supported important research on mental health topics including studies on children's mental health issues, the impact of mental health parity on consumers' share of mental health costs, improving care for depression in primary care, and cultural issues in the treatment of mental illness in minority populations. This work has led to important contributions to the mental health literature, and the advancement of effective diagnosis and treatment of mental illness. We applaud these efforts and urge the Committee to increase support for the critical work of this Agency.

However, we are concerned that the research agenda of the Agency has not given more attention to geriatric mental health issues. The prevalence of undiagnosed and untreated mental illness among the elderly is alarming. Conditions such as depression, anxiety, dementia, and substance abuse in older adults are often misdiagnosed or not recognized at all by primary and specialty care physicians. There is accumulating evidence that depression can exacerbate the effects of cardiac disease, cancer, strokes, and diabetes. Research has also shown that treatment of mental illness can improve health outcomes for those with chronic diseases. Effective treatments for mental illnesses in the elderly are available, but without access to physicians and other health professionals with the training to identify and treat these conditions, far too many seniors fail to receive needed care.

AAGP believes there is an urgent need to translate findings from aging-related biomedical and behavioral research into geriatric mental health care. By utilizing the resources of the evidence-based practice centers under contract to AHRQ, results from geriatric mental health research can be evaluated and translated into findings that will improve access, foster appropriate practices, and reduce unnecessary and wasteful health care expenditures. We urge the Committee to direct AHRQ to support additional research projects focused on the diagnosis and treatment of mental illnesses in the geriatric population. We also believe a high priority should be given to the dissemination of scientific findings about what works best, to encourage physicians and other health professionals to adopt "best practices" in geriatric mental health care.

Conclusion

Based on AAGP's assessment of the current need and future challenges of late life mental disorders, we submit the following fiscal year 2004 funding recommendations:

The current rate of funding for aging grants at NIMH and CMHS is inadequate. Funding for NIMH and CMHS aging-related research grants should be increased to be commensurate with current need—at least three times their current funding levels. In addition, the substantial projected increase in mental disorders in our aging population should be reflected in the budget process in terms of dollar amount of grants and absolute number of new grants.

A fair grant review process will be enhanced by committees with specific expertise and dedication to mental health and aging;

Infrastructure and reporting mechanisms within NIMH and CMHS are essential to support the development of initiatives in aging research, to monitor the number and quality of applicants for aging research grants, to promote funding of meritorious projects, and to manage those grant portfolios. Those individuals in the Office of the Director of NIMH and in the Office of the Director of CMHS who are designated to oversee the aging research agendas and initiatives for these two agencies should provide regular reports to Congress to ensure accountability;

AHRQ should undertake additional research projects focused on the diagnosis and treatment of mental illnesses in the geriatric population, and dissemination of information on best practices; and

Funding for NIAAA must be increased by at least 20 percent to enable it to undertake more research and collect more data focused on issues such as the link between alcohol use and late-life suicide and the impact of alcohol use across the lifespan.

AAGP strongly believes that the present research infrastructure, professional workforce with appropriate geriatric training, health care financing mechanisms, and mental health delivery systems are grossly inadequate to meet the challenges posed by the expected increase in the number of older Americans with mental disorders. Congress must support funding for research that addresses the diagnosis and treatment of mental illnesses, as well as programs for delivery of geriatric mental health services that increase the quality of life for those with late-life mental illness.

AAGP looks forward to working with the members of this Subcommittee and others in Congress to establish geriatric mental health research and services as a priority at NIMH, CMHS, AHRQ and NIAAA.

PREPARED STATEMENT OF THE HEPATITIS FOUNDATION INTERNATIONAL

SUMMARY OF FISCAL YEAR 2004 RECOMMENDATIONS

Continue the great strides in research and prevention at the National Institutes of Health (NIH) by providing a 10 percent budget increase for fiscal year 2004. Increase funding for the National Institute for Allergy and Infectious Diseases (NIAID) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) by 10 percent.

[In billions of dollars]

NIIH	29.8
NIAID	[1] 3.9
NIDDK	1.7

[1] Non-bioterrorism.

—Provide $7.9 billion in fiscal year 2004 for the Centers for Disease Control and Prevention (CDC).
—Provide $41 million in fiscal year 2004 for a hepatitis B vaccination program for high risk adults at CDC as recommended by the National Hepatitis C Prevention Strategy.
—Provide $40 million in fiscal year 2004 for CDC's Prevention Research Centers.
—Provide continued support of the National Viral Hepatitis Roundtable.

Chairman Specter and members of the subcommittee thank you for your continued leadership in promoting better research, prevention, and control of diseases affecting the health of our nation. I am Thelma King Thiel, Chairman and Chief Executive Officer of the Hepatitis Foundation International (HFI), representing members of 425 patient support groups across the nation, the majority of whom suffer from chronic viral hepatitis.

Currently, five types of viral hepatitis have been identified, ranging from type A to type E. All of these viruses cause acute, or short-term, viral hepatitis. Hepatitis B, C, and D viruses can also cause chronic hepatitis, in which the infection is prolonged, sometimes lifelong. While treatment options are available for all types of hepatitis, individuals with chronic viral hepatitis (types B, C, and D) represent the majority of liver failure and transplant patients. Treatment options and immunizations are available for most types of hepatitis (see below), however, all types of viral hepatitis are preventable.

HEPATITIS B

Hepatitis B (HBV) claims an estimated 5,000 lives every year in the United States, even though we have therapies to both prevent and treat this disease. This disease is spread through contact with the blood and body fluids of an infected individual. Unfortunately, due to both a lack in funding to vaccinate adults at high risk of being infected and the absence of an integrated preventive education strategy transmission of hepatitis B continues to be problematic.

HEPATITIS C

Infection rates for hepatitis C (HCV) are at epidemic proportions. Unfortunately, as many do not become ill with the disease until several years after infection, we are dealing with an "epidemic of discovery". This creates a vicious cycle, as individuals who are infected continue to spread the disease, unknowingly. Hepatitis C is also spread through contact with an infected individual's blood. The CDC estimates that there are over 4 million Americans who have been infected with hepatitis C, of which over 2.7 million remain chronically infected, with 8,000–10,000 deaths each year. Additionally, the death rate is expected to triple by 2010 unless additional steps are taken to improve outreach and education on the prevention of hepatitis C, new research is undertaken, and case-finding is enhanced and more effective treatments are developed. As there is no vaccine for HCV, prevention activities serve as the only tool in halting the spread of this disease.

PREVENTION IS THE KEY

Only a major investment in immunization and preventive education will bring these diseases under control. All newborns, young children, young adults, and especially individuals that participate in high-risk behaviors must be a priority for immunization, outreach initiatives and preventive education. We recommend that the following activities be undertaken to prevent the further spread of all types of hepatitis:

—Provide effective preventive education in our elementary and secondary schools helping children avoid the ravages of health problems resulting from viral hepatitis infection.
—Training educators and health care professionals in effective communication and counseling techniques.
—Public awareness campaigns to alert individuals to assess their own risk behaviors, motivate them to seek medical advice, encourage immunization against hepatitis A and B, and to stop the consumption of any alcohol if they have participated in risky behaviors that may have exposed them to hepatitis C.
—Expansion of screening, referral services, medical management, counseling, and prevention education for individuals who have HIV/AIDS, many of whom may be co-infected with hepatitis.

HFI recommends an increase of $41 million in fiscal year 2004 for further implementation of CDC's Hepatitis C Prevention Strategy. This increase will support and expand the development of state-based prevention programs by increasing the number of state health departments with CDC funded hepatitis coordinators. The Strategy will use the most cost-effective way to implement demonstration projects evaluating how to integrate hepatitis C and hepatitis B prevention efforts into existing public health programs. Additionally, HFI recommends that $10 million be used to train and maintain hepatitis coordinators in every state.

CDC's Prevention Research Centers, an extramural research program, plays a critical role in reducing the human and economic costs of disease. Currently, CDC funds 26 prevention research centers at schools of public health and schools of medicine across the country. HFI encourages the Subcommittee to increase core funding for these prevention centers, as it has been decreasing since this program was first funded in 1986. We recommend the Subcommittee provide $40 million for the Prevention Research Centers program in fiscal year 2004.

INVESTMENTS IN RESEARCH

Investment in the National Institutes of Health (NIH) has led to an explosion of knowledge that has advanced understanding of the biological basis of disease and development of strategies for disease prevention, diagnosis, treatment, and cures. Countless medical advances have directly benefited the lives of all Americans. NIH-supported scientists remain our best hope for sustaining momentum in pursuit of scientific opportunities and new health challenges. For example, research into why some HCV infected individuals resolve their infection spontaneously may prove to be life saving information for others currently infected. Other areas that need to be addressed are:

—Reasons why African Americans do not respond to antiviral agents in the treatment of chronic hepatitis C.
—Pediatric liver diseases, including viral hepatitis.
—The outcomes and treatment of renal dialysis patients who are infected with HCV.
—Co-infections of HIV/HCV and HIV/HBV positive patients.
—Hemophilia patients who are co-infected with HIV/HCV and HIV/HBV.
—The development of effective treatment programs to prevent recurrence of HCV infection following liver transplantation.
—The development of effective vaccines to prevent HCV infection.

The Hepatitis Foundation International supports a 10 percent increase, which would provide $29.78 billion for NIH in fiscal year 2004. HFI also recommends a comparable increase of 10 percent in hepatitis research funding at the National Institute of Diabetes and Digestive and Kidney Diseases and the National Institute of Allergy and Infectious Diseases.

NATIONAL VIRAL HEPATITIS ROUNDTABLE

Victims of hepatitis suffer emotionally as well as physically. They experience discrimination in employment, strained personal relationships and severe depression when treatments fail to control their illness as well as during their treatment. Traditionally, however, there has not been an organized effort to periodically convene

all stakeholder organizations that play a role in hepatitis prevention, education, treatment and patient advocacy. Successfully addressing viral hepatitis will require a comprehensive and strategic approach developed by all key stakeholders.

In order to fill this void, HFI and CDC co-founded the "National Viral Hepatitis Roundtable". HFI believes that a National Viral Hepatitis Roundtable will enhance and assist CDC's viral hepatitis mission for the prevention, control, and elimination of hepatitis virus infections in the United States, as well as the international public health community. It will provide an infrastructure for the sharing of information and education of all stakeholders.

The "National Viral Hepatitis Roundtable" is a coalition of public, private, and voluntary organizations dedicated to reducing the incidence of infection, morbidity, and mortality from viral hepatitis in the United States through research, strategic planning, coordination, advocacy, and leadership.

This organization acts in an advisory capacity to all parties interested in topics pertaining to viral hepatitis. The Roundtable first convened on January 13, 2003.

HFI is dedicated to the eradication of viral hepatitis, which affects over 500 million people around the world. We seek to raise awareness of this enormous worldwide problem and to motivate people to support this important—and winnable—battle. Thank you for providing this opportunity to present our testimony.

THE HEPATITIS FOUNDATION INTERNATIONAL

The Hepatitis Foundation International (HFI) is dedicated to the eradication of viral hepatitis, a disease affecting over 500 million people around the world. We seek to raise awareness of this enormous worldwide problem and to motivate people to support this important—and winnable—battle.

Our mission has four distinct parts:

—Teach the public and hepatitis patients how to prevent, diagnose, and treat viral hepatitis.

—Prevent viral hepatitis by promoting liver wellness and healthful lifestyles.

—Serve as advocates for hepatitis patients and the related medical community worldwide.

Support research into prevention, treatment, and cures for viral hepatitis.

PREPAED STATEMENT OF THE FACIOSCAPULOHUMERAL MUSCULAR DYSTROPHY SOCIETY

Mr. Chairman, it is a great pleasure to submit this testimony to you today.

My name is Daniel Paul Perez, of Lexington, Massachusetts, and I am testifying as President & Chief Executive Officer of the FacioScapuloHumeral Muscular Dystrophy Society (FSH Society, Inc.) and as an individual who has this devastating disorder.

Facioscapulohumeral muscular dystrophy (FSHD) is the third most prevalent form of muscle disease. FSHD is a neuromuscular disorder that is transmitted genetically to 1/20,000 people. It affects up to 37,500 persons in the United States. FSHD can occur at any time by new mutations in the chromosome. 20–30 percent of people affected by FSHD are believed to be new mutations. For men and women, the major consequence of inheriting FSHD is progressive and severe loss of skeletal muscle. The usual pattern is of initial noticeable weakness of facial, scapular and upper arm muscles and subsequent weaknesses of other skeletal muscles. Retinal and cochlear disease can often be associated with FSHD although the pathogenesis and causative relationship to FSHD remains unknown. FSHD wastes the skeletal muscles and gradually but surely brings weakness and reduced mobility. Many with FSHD are severely physically disabled and spend the last 30 years of their lives in a wheelchair. The toll and cost of FSHD physically, emotionally and financially are enormous. FSHD is a life long disease that has an enormous cost-of-disease burden and is a life sentence for the innocent patient and involved persons and their children and grandchildren as well.

People who have FSHD must cope with continuing, unrelenting and never-ending losses. The most unlucky, those who are affected from birth, are deprived of virtually all the ordinary joys and pleasures of childhood and adolescence. No matter at which stage of life the disease makes itself known, there is never after that any reprieve from continuing loss of physical ability or ever for a moment relief from the physical and emotional pain that FSHD brings in its train. Every morning, FSHD sufferers wake up to face the reality that neither a cause for their disease nor any treatment for it has yet been found.

FSHD denies a person the full range of choices in life. FSHD affects the way you walk, the way you dress, the way you work, the way you wash, the way you sleep,

the way you relate, the way you parent, the way you love, the way and where you live, the way people perceive you, interact with you and treat you. You cannot smile, hold a baby in your arms, close your eyes to sleep, run, walk on the beach or climb stairs. Each new day brings renewed awareness of the things you may not be able to do the next day. This is what life is for tens of thousands of people affected by FSHD worldwide.

Through the FSH Society, FSHD patients have found ways to be useful to medical and clinical researchers working on their disease. The FSH Society acts as a clearinghouse for information on the FSHD disorder and on potential drugs and devices designed to alleviate its effects. It fosters communication among FSHD patients, their families and caregivers, charitable organizations, government agencies, industry, scientific researchers and academic institutions. It solicits grants and contributions from members of the FSH Society, and from foundations, the pharmaceutical industry, and others to support scientific research and development. It makes grants and awards to qualified research applicants. In less than six years, the FSH Society has raised more than $1.1 million for research and has invested it in more than two dozen innovative research programs internationally. One of the FSH Society's key assets, its Scientific Advisory Board, is composed of international experts whose awareness of current FSHD research ensures both that new research is not duplicative but complementary and that it will fill gaps in existing knowledge. The FSH Society's work in education, advocacy, and training has led to increased funding in the United States and abroad. It was a key participant in drafting the Muscular Dystrophy Community Assistance Research and Education Act of 2001 (MD CARE Act) which in the United States mandates research and investigation into all forms of Muscular Dystrophy.

A decade of progress in FSHD has led to the discovery of many novel genetic phenomena never seen before in human disease and genomics. Despite remarkable genetic insight and immense progress by a small team of scientists worldwide, the nature of the gene products remain enigmatic and the biochemical mechanism and cause of this common muscle disease remains unknown and elusive. The same is true for any treatment—none exist.

More than a decade ago, we appeared before this Committee to testify for the first time. Ten years ago, I walked with some difficulty. Today, I sit in a wheelchair because of this disease called FSHD. Over the same ten years, the Appropriations Committees in both the U.S. House and the U.S. Senate have repeatedly instructed the National Institutes of Health (NIH) to enhance and broaden the portfolio in FSHD and muscular dystrophy in general. The NIH accounting for the total overall NIH and the subset of muscular dystrophy appropriations in millions of dollars for the past five years follows:

NATIONAL INSTITUTES OF HEALTH (NIH) APPROPRIATIONS HISTORY

[Dollars in millions]

Fiscal year	NIH overall dollars	MD research dollars	MD percent of NIH	FSH research dollars	FSHD percent of MD	FSHD percent of NIH
1999	$15,629	$16.7	0.107	$0.4	2.39	0.0026
2000	17,821	12.6	0.071	0.4	3.18	0.0022
2001	20,458	21.0	0.103	0.5	2.38	0.0024
2002	23,296	27.6	0.118	1.3	4.71	0.0056
2003	27,067	31.4	0.116	1.5	4.78	0.0055

Source: NIH/OD Budget Office & NIH CRISP Database On-line.

Despite major initiatives from the volunteer health agencies and the extramural community of researchers, FSHD research at the NIH and funding through the NIH is negligible in muscular dystrophy. Notwithstanding these positive changes at the NIH as well as major cooperative initiatives from the volunteer health agencies and the extramural community of researchers, we realize that major changes are slow but we are hopeful that this year the NIH will initiate new and increased funding for FSHD.

NATIONAL INSTITUTES OF HEALTH (NIH) R21, R01, P01 GRANTS FOR FSHD

Fiscal year(s)	Total No. of FSHD P01 grants	Total No. of FSHD R01 grants	Total No. of FSHD R21 grants
1972–1998	.....	3	.....
1999	.....	1	.....
2000	.....	1	.....
2001	.....	1	
2002	.....	.....	6
2003	.....	.....	7

Source: NIH CRISP Database On-line.

Our concern is that the funding increases for facioscpaulohumeral muscular dystrophy (FSHD) have been abysmal. In the last eighteen months, four grants directly and specifically pertaining to FSHD were submitted. One of the four, a small R21 style grant, was funded by the NIH Committee for Scientific Review (CSR). Despite the Congressional mandate to accelerate research on FSHD, FSHD grant applications are still not making it through the peer review process. FSHD grant reviews have been a constant source of frustration for FSHD researchers submitting grant applications to the program and review staff of CSR. Submitting R01, P01, R21 grant applications calls/contracts has been a frustrating and time consuming endeavor for most researchers in the FSHD community since it bears little fruit. Since 1994, not a single R01 or P01 grant application focusing directly on a critical aspect of FSHD has survived the peer review process at CSR despite the high quality of researchers and the leading edge of scientific thought and opportunity involved with FSHD. We choose not to disagree with the peer review process at NIH nor do we seek to change the peer review requirement. However, we strongly emphasize that there is a shortage of reviewers with the required expertise to guarantee the review deserved by grant submissions in the muscular dystrophy area. Review of FSHD proposals, with novel genetic phenomena and mechanisms and a leading edge of scientific thought, are particularly needful of that expertise. This should be addressed through training, development and mentorship programs by the NIH. We also emphasize that the NIH must offer ways to ameliorate the difficulties in this aspect through targeted programs, training scientists and short and long term outreach efforts to produce the desired input to its own NIH process.

Congress has been very generous with the NIH. Congress has repeatedly mandated more effort in muscular dystrophy research in general and FSHD research in particular. But this is not happening.

We ask Congress to investigate why this is happening and request an explanation from the NIH accounting for the failure to do better in the area of FSHD despite repeated Congressional requests. Three R01 research grants funded on FSHD (two of them only peripherally FSHD-related at best) in four decades is not enough. We implore Congress to request the NIH to specifically build the research portfolio on FSHD through all available means, including re-issuing specific calls for research on FSHD at an accelerated rate, to make up for historical neglect.

Mr. Chairman, we trust your judgment on the matter before us. We believe the Committee should explore why muscular dystrophy in general and FSHD in particular has been left behind in the great rise in research support at the NIH. Frankly, we are extremely frustrated that amid a huge increase in funding and strong unambiguous expressions of Congressional support, the NIH commitment in facioscapulohumeral muscular dystrophy (FSHD) is so weak. Only you can answer that question.

Mr. Chairman, again, thank you for providing this opportunity to testify before your Subcommittee.

PREPARED STATEMENT OF THE INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

SUMMARY OF FISCAL YEAR 2004 RECOMMENDATIONS

—Provide a 10 percent increase, to $29.8 billion, for fiscal year 2004 to the National Institutes of Health (NIH) budget. Within NIH, provide proportional increases of 10 percent to the various institutes and centers, specifically, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). We request NIDDK's budget to be increased by 10 percent to $1.7 billion.

—Continue to accelerate funding for extramural clinical and basic functional gastrointestinal research at NIDDK.
—Provide funding for NIDDK to conduct a prevalence study on and to increase public and professional awareness of irritable bowel syndrome (IBS).
—Provide funding for NIDDK to work to develop a strategic plan setting research goals on IBS and functional bowel diseases and disorders.
—Provide funding to NIDDK and the National Cancer Institute (NCI) for more research on the causes of esophageal cancer.

Chairman Specter and members of the Subcommittee, thank you for the opportunity to present this written statement regarding the importance of functional gastrointestinal and motility research.

My name is Nancy Norton, and in 1991, I founded the International Foundation for Functional Gastrointestinal Disorders (IFFGD), in response to my own experiences as a patient. I'm proud to say that 12 years later my organization serves hundreds of thousands of people in need each year, providing information and support to patients and physicians. The largest organization of its kind in the world, IFFGD works with consumers, patients, physicians, providers and payers to broaden understanding about fecal incontinence, irritable bowel syndrome (IBS), gastroesophageal reflux disease (GERD), pediatric disorders and numerous other gastrointestinal disorders. Additionally, it has been my personal vision and goal to see a greater investment in research on functional gastrointestinal and motility disorders.

IFFGD continues to speak about and raise awareness for disorders and diseases that many people are uncomfortable and embarrassed to talk about. The prevalence of fecal incontinence and irritable bowel syndrome, as well as a host of other gastrointestinal disorders affecting both adults and children, is underestimated in the United States. These conditions are truly hidden in our society. Not only are they misunderstood, but the burden of illness and human toll has not been fully recognized.

Given that we have been diligently working for the past twelve years it is an exciting time to lead the IFFGD, not only are we serving more and more people, but we are beginning to be able to privately fund research. Our first research awards were made on April 6, 2003.

Since its establishment the IFFGD has been dedicated to increasing awareness of functional gastrointestinal disorders and motility disorders, among the public, health professionals, and researchers. Last November, we hosted a conference on fecal and urinary incontinence. During the first week of April 2003 we also hosted the Fifth International Symposium on Functional Gastrointestinal Disorders, which was a great success in bringing scientists from across the world together to discuss the current science and opportunities on irritable bowel syndrome and other functional gastrointestinal and motility disorders. The IFFGD has become known for our professional symposia. We consistently bring together a unique group of international multidisciplinary investigators to communicate new knowledge in the field of gastroenterology.

The majority of the diseases and disorders we address have no cure. We have yet to understand the pathophysiology of the underlying conditions. Patients face a life of learning to manage chronic illness that is accompanied by pain and an unrelenting myriad of gastrointestinal symptoms. The costs associated with these diseases are enormous, conservative estimates range between $25–$30 billion annually. The human toll is not only on the individual but also on the family. Economic costs spill over into the workplace. In essence these diseases reflect lost potential for the individual and society. The IFFGD is a resource and provides hope for hundreds of thousands of people as they try to regain as normal a life as possible.

FECAL INCONTINENCE

I have had IBS most of my adult life and due to an obstetrical injury 17 years ago I now live with bowel incontinence. Incontinence in particular is often thought of as something that affects us when we are frail and elderly—perhaps something that is part of the aging process.

At least 6.5 million Americans suffer from fecal incontinence. Incontinence is neither part of the aging process nor is it something that affects only the elderly. Incontinence crosses all age groups from children to older adults, but is more common among women and in the elderly of both sexes. Often it is a symptom associated with various neurological diseases and many cancer treatments. Yet, as a society, we rarely hear or talk about the bowel disorders associated with multiple sclerosis, diabetes, colon cancer, uterine cancer, and a host of other diseases, let alone a complication of an episiotomy with vaginal delivery.

Fecal incontinence can be caused by: damage to the anal sphincter muscles; damage to the nerves of the anal sphincter muscles or the rectum; loss of storage capacity in the rectum; diarrhea; or pelvic floor dysfunction. People who have fecal incontinence may feel ashamed, embarrassed, or humiliated. Some don't want to leave the house out of fear they might have an accident in public. Most try to hide the problem as long as possible, so they withdraw from friends and family. The social isolation is unfortunate but may be reduced because treatment can improve bowel control and make incontinence easier to manage.

IRRITABLE BOWEL SYNDROME (IBS)

Irritable Bowel Syndrome affects approximately 30 million Americans. This chronic disease is characterized by a group of symptoms, which can include abdominal pain or discomfort associated with a change in bowel pattern, such as loose or more frequent bowel movements, diarrhea, and/or constipation. Although the cause of IBS is unknown, we do know that this disease needs a multidisciplinary approach in research and treatment.

Similar to fecal incontinence and depending on severity, IBS can be emotionally and physically debilitating. Because of persistent bowel irregularity, individuals who suffer from this disorder may distance themselves from social events, work, and even may fear leaving their home.

GASTROESOPHAGEAL REFLUX DISEASE (GERD)

Gastroesophageal reflux disease, or GERD, is a very common disorder affecting both adults and children, which results from the back-flow of acidic stomach contents into the esophagus. GERD is often accompanied by persistent symptoms, such as chronic heartburn and regurgitation of acid. But sometimes there are no apparent symptoms, and the presence of GERD is revealed when complications become evident. Symptoms of GERD vary from person to person. The majority of people with GERD have mild symptoms, with no visible evidence of tissue damage and little risk of developing complications.

Periodic heartburn is a symptom that many people experience. There are several treatment options available for individuals suffering from GERD.

Gastroesophageal reflux (GER) affects as many as one third of all full term infants born in America each year. GER results from an immature upper gastrointestinal motor development. The prevalence of GER is increased in premature infants. Many infants require medical therapy in order for their symptoms to be controlled. Up to 25 percent of older children and adolescents will have GER or GERD due to lower esophageal sphincter dysfunction. In this population, the natural history of GER is similar to that of adult patients, in whom GER tends to be persistent and may require long-term treatment.

ESOPHAGEAL CANCER

Approximately 13,000 new cases of esophageal cancer are diagnosed every year in this country. Although the causes of this cancer are unknown, it is thought that this cancer may be more prevalent in individuals who develop Barrett's esophagus. Diagnosis usually occurs when the disease is in an advanced stage, early screening tools are currently unavailable.

CHILDHOOD DEFECATION DISORDERS AND DISEASES

Chronic Intestinal Pseudo-Obstruction (CIP).—About 200 new cases of CIP are diagnosed in American Children each year. Often life threatening, the future for children severely affected with CIP is brightened by the evolving promise of cure with intestinal or multi-organ transplantation.

Hirschsprung's disease.—A serious childhood and sometimes life-threatening condition that can cause constipation, occurs only once in every 5,000 American children born each year. Approximately 20 percent of children with HD will continue to have complications following surgery. These complications include infection and/or fecal incontinence.

Functional constipation.—Millions of children (1 in every 10) each year will be diagnosed with functional constipation. In fact, it is the chief complaint of 3 percent of pediatric outpatient visits and 10–25 percent of pediatric gastroenterology visits.

FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS AND THE NATIONAL INSTITUTES OF HEALTH

The International Foundation for Functional Gastrointestinal Disorders recommends an increase to $29.8 billion or 10 percent for NIH overall, and a 10 per-

cent increase for NIDDK, or $1.7 billion. However, we request that this increase for NIH does not come at the expense of other Public Health Service agencies.

We urge the subcommittee to provide the necessary funding for the expansion of the NIDDK's research program on functional gastrointestinal (FGI) and motility disorders, this increased funding will allow for the growth of new research, a prevalence study and a strategic plan on IBS, and increased public and professional awareness of FGI and motility disorders.

A primary tenant of IFFGD's mission is to ensure that clinical advancements concerning GI disorders result in improvements in the quality of life of those affected. By working together, this goal will be realized and the suffering and pain millions of people face daily will end.

Thank you.

THE INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

The International Foundation for Functional Gastrointestinal Disorders is a non-profit education and research organization founded in 1991. IFFGD addresses the issues surrounding life with gastrointestinal (GI) functional and motility disorders and increases the awareness about these disorders among the general public, researchers, and the clinical care community.

PREPARED STATEMENT OF THE NEPHCURE FOUNDATION

SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2004

1. A 10 PERCENT INCREASE FOR THE NATIONAL INSTITUTES OF HEALTH AND THE NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK).
2. ENCOURAGE NIDDK TO PROVIDE HIGH PUBLIC VISIBILITY FOR GLOMERULAR DISEASE AS PART OF THE FORTHCOMING NATIONAL KIDNEY DISEASE EDUCATION PROGRAM.
3. ENCOURAGE THE NATIONAL CENTER FOR MINORITY HEALTH AND HEALTH DISPARITIES (NCMHD) TO INITIATE STUDIES INTO THE INCIDENCE/CAUSE OF FOCAL SEGMENTAL GLOMERULOSCLEROSIS (FSGS) IN THE AFRICAN-AMERICAN POPULATION.
4. PRIORITIZE, AT NIDDK, A PROGRAM FOR COLLECTION OF TISSUE SAMPLES AND SCIENTIFIC RESEARCH INTO THE CAUSE OF FSGS, BUILDING ON THE CURRENT FSGS CLINICAL TRIALS UNDERWAY. THUS, HEIGHTENING THE ATTRACTION OF GLOMERULAR INJURY RESEARCH FOR TALENTED RESEARCHERS.

Mr. Chairman, and members of the subcommittee, I am pleased to present testimony on behalf of the NephCure Foundation (NCF), a non-profit organization driven by a blue-ribbon panel of respected medical experts and a dedicated band of patients and families working for a common goal—to save kidneys and lives.

I also include a letter from Melanie Stewart, one of tens of thousands of young Americans struggling with an insidious disease of the kidney's filtering mechanism. Now living with the aid of daily dialysis, Melanie relates just a little of her courageous battle with focal segmental glomerulosclerosis, or FSGS.

Treatment Trials Beginning, But No Cure in Sight

Mr. Chairman, FSGS is one of a cluster of glomerular diseases that attack the one million tiny filtering units contained in each human kidney. These filters are called nephrons and the diseases attack the portion of the nephron called the glomerulus, scarring and often destroying the irreplaceable filters. Scientists don't know why glomerular injury occurs and they are not sure how to stop its destruction of the kidney.

We are thankful that an NIDDK-funded clinical trial will begin this year to study the efficacy of the current treatments for FSGS. But these clinical trials hold out no particular hope for patients such as my 18-year-old daughter, Christine, who also suffers from FSGS. Chrissy has been treated with most of the drugs that will be tested in the upcoming clinical trial. Thus far, none have stopped the proteinuria; the spilling of protein in the urine that characterizes glomerular injury.

Christine has experienced the facial swelling and disfigurement that periodically comes and goes with glomerular disease. She has suffered the depression and mental ravages of heavy steroid treatments. Nothing has worked. Last year her kidneys showed scarring and today she is one of thousands of young people who are in a race against time, hoping for a treatment that will save her kidneys. The NephCure

Foundation today raises its voice to speak for them all, asking you for specific actions that will aid our quest to find the cause and the cure.

First and foremost, we support a 10 percent increase for the National Institutes of Health and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

Too Little Data About a Growing Problem

When glomerular disease strikes, the resultant Nephrotic Syndrome causes loss of protein in the urine and symptoms such as edema, a swelling that often appears first in the face. The Antosh family physician mistook Christine's puffy eyelids as an allergy symptom. Stories of similar misdiagnosis are common at our Foundation. With experts projecting a substantial increase in Nephrotic Syndrome in coming years, there is a clear need to educate pediatricians and family physicians about glomerular disease and its symptoms.

The NephCure Foundation has numerous education programs underway, including patient education seminars, the most recent of which is slated for Seattle in May. News of our activities can be found on our web site at www.nephcure.org. But our efforts are not enough.

As NIDDK plans a major federal outreach—the National Kidney Disease Education Program—we seek your support in urging NIDDK to assure that glomerular disease receives high visibility in this important program.

Glomerular Disease Strikes Minority Population

Nephrologists tell us that glomerular diseases such as FSGS affect a disproportionate number of African-Americans and, according to NIDDK, "the worst prognosis is observed in African-American children." NephCure officials have described this situation in a meeting with Dr. John Ruffin, director of the National Center for Minority Health and Health Disparities (NCMHD).

As the NCMHD becomes fully operational and plans programs, our Foundation will continue to work with the Center to encourage the creation of programs to study the high incidence of glomerular disease within the African-American population.

We ask the Committee to join with us in requesting that the National Center for Minority Health and Health Disparities seize the opportunity to establish research into the phenomenon of glomerular disease with in the African American community.

More Basic Science is Needed

The current FSGS clinical trials, which will cover an estimated 400 patients over a three year period, are limited, according to the RFA, to examining the "impact of immunomodulatory therapy on proteinuria." While the trials may lead to safer or more efficient care for children with FSGS, no one is suggesting that they will bring us closer to finding the cause and cure. Science has yet to prove that FSGS is an immune-mediated disease.

Scientists tell us that much more needs to be done in the area of basic science, beginning with collection of tissue and fluid samples from a large number of patients on which years of important scientific research can be founded. NephCure is collaborating with the NIH in a major way to work for such progress.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) will match, dollar-for-dollar, funds raised by NephCure that will allow researchers to obtain DNA samples from hundreds of FSGS patients in upcoming clinical trials. The NIDDK will match up to $300,000 raised by NephCure for a combined total of $600,000.

We urge you to prioritize a program for a comprehensive study of such tissue samples and other new programs of scientific research into the cause of FSGS at NIDDK, actions that will enhance the attraction of glomerular injury research for talented researchers.

We sincerely believe that the recommendations we make here today, if implemented, will give hope to the thousands of young people whose kidneys and lives are threatened by this terrible disease, and give meaning and honor to the heroic story of Melanie Stewart.

Hello, my name is Melanie Stewart. I'm 15 years old and have been fighting FSGS since I was seven. Over the last 8 years, I've spent most of my time in the hospital or hooked up to a dialysis machine, while trying to keep up my schoolwork. It hasn't been easy.

Three years ago, FSGS destroyed both of my kidneys. On April 21, 1999, my dad gave me one of his kidneys. The year after the transplant was one of the hardest. Over that time I had Apheresis procedures done three times a week. As a result of the high doses of immune suppressant drugs, PTLD, a form of cancer, was found

on my head. In November of 2000, I almost died because of a blood infection and a blood clot in my heart caused by the Apheresis catheter.

In March of 2001, I had my donated kidney removed. I am now on dialysis again, every day, and am forced to start over.

There are thousands of people, mostly young, like me who would like a chance for a cure and a normal life.

For everyone, I'm asking for your help to help me meet my goal of finding a cure.

Thank you for allowing me to share my story and thank you for listening.

PREPARED STATEMENT OF THE CHARLES R. DREW UNIVERSITY OF MEDICINE AND SCIENCE

SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2004

—10 PERCENT INCREASE FOR THE NATIONAL INSTITUTES OF HEALTH AS WELL AS A 10 percent INCREASE FOR ALL INSTITUTES AND CENTERS, SPECIFICALLY THE NATIONAL CENTER FOR RESEARCH RESOURCES (NCRR), THE NATIONAL CENTER FOR MINORITY HEALTH AND HEALTH DISPARITIES (NCMHD), AND THE NATIONAL CANCER INSTITUTE (NCI).

—URGE NCRR, NCMHD, AND NCI TO WORK TOGETHER TO SUPPORT THE ESTABLISHMENT OF A NATIONAL MINORITY HEALTH COMPREHENSIVE CANCER CENTER AT A HISTORICALLY MINORITY INSTITUTION.

Mr. Chairman and members of the subcommittee, I am Dr. Charles Francis, President of Charles R. Drew University of Medicine and Science. Charles R. Drew University is one of four predominantly minority medical schools in the country, and the only one located west of the Mississippi River.

Charles R. Drew University of Medicine and Science is located in the Watts-section of South Central Los Angeles, and has a mission of rendering quality medical education to underrepresented minority students, and, through its affiliation with the University of California Los Angeles (UCLA) at the co-located King-Drew Medical Center, Drew provides valuable health care services to the medically underserved community. Through innovative basic science, clinical, and health services research programs, Drew University works to address the health and social issues that strike hardest and deepest among inner city and minority populations.

The population of this medically underserved community is predominately African American and Hispanic. Many of these people would be without health care if not for the services provided by the King-Drew Medical Center and Charles R. Drew University of Medicine and Science. This record of service has led Charles R. Drew University (in partnership with UCLA School of Medicine) to be designated as a Health Resources and Services Administration Minority Center of Excellence.

A RESPONSE TO HEALTH DISPARITIES

Racial and ethnic disparities in health care have long been established as a major barrier to successful prevention and treatment of a multitude of diseases in minority and underserved communities. As recently articulated in the Institute of Medicine report entitled "Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care", this problem is not getting better on its own. For example, African American males develop cancer fifteen percent more frequently than white males. Similarly, African American women are not as likely as white women to develop breast cancer, but are much more likely to die from the disease once it is detected. In fact, according to the American Cancer Society, those who are poor, lack health insurance, or otherwise have inadequate access to high-quality cancer care, typically experience high cancer incidence and mortality rates. Despite these devastating statistics, we are still not doing enough to try to combat cancer in our communities.

In response to these findings and the high cancer rate in their own community, Charles R. Drew University of Medicine and Science proposes that a Minority Health Comprehensive Cancer Center be built on its campus.

The Center would specialize in providing not only medical treatment services for the community, but would also serve as a research facility, focusing on prevention and the development of new strategies in the fight against cancer.

SUPPORT FOR THIS INITIATIVE

Mr. Chairman, the support that this subcommittee has given to the National Institutes of Health (NIH) and its various Institutes and Centers has and continues to be invaluable to our University and our community. The dream of a state of the

art facility to aid in the fight against cancer in our underserved community would be impossible without the resources of NIH.

To help facilitate the establishment of a Minority Health Comprehensive Cancer Center at Charles R. Drew University of Medicine and Science, the University is seeking support from the National Institutes of Health's National Center for Research Resources (NCRR), the National Center for Minority Health and Health Disparities (NCMHD), and the National Cancer Institute (NCI).

First, the facility must be constructed. Drew University does meet the Public Health Service Act eligibility requirement for facilities construction grants which maintains that the institution "is located in a geographic area in which a deficit in health care technology, services, or research resources may adversely affect health status of the population of the area in the future, and the applicant is carrying out activities with respect to protecting the health status of such a population." Therefore, the university is seeking Extramural Facilities Construction grants through NCRR in the amount of $4 million per grant cycle for build-out of the first floor of the research facility, and subsequent build-out of the second floor.

The University is also seeking $8 million from NCMHD for the research building shell to house the Charles R. Drew University of Medicine and Science Minority Health Comprehensive Cancer Center.

In addition, the Minority Health Comprehensive Cancer Center cannot become a reality without programmatic funding. Drew University, in collaboration with UCLA, is seeking support from NCI in the amount of $10 million over five years to support the health care and research activities conducted by the Center.

CONCLUSION

Despite our knowledge about the disparities in diseases and health care, the "gap" continues to widen. Not only are minority and underserved communities burdened by higher disease rates, they are less likely to have access to quality care upon diagnosis. As you are aware, in many minority and underserved communities preventive care and/or research is completely inaccessible either due to distance or lack of facilities and expertise.

Even though institutions like Drew are ideally situated (by location, population, and institutional commitment) for the study of conditions in which health disparities have been well documented, research is limited by the lack of appropriate research facilities. With your help, this cancer center will facilitate translation of insights gained through research into greater understanding of disparities in cancer incidence, morbidity and mortality and ultimately to improved outcomes.

Mr. Chairman, with your support and the financial resources of NIH, Charles R. Drew University of Medicine and Science can not only be the nation's first Historically Black College or University (HBCU) to have a Comprehensive Cancer Center, but also the first minority medical school in the country to have a comprehensive cancer center focused exclusively on minority health and health disparities.

We look forward to working with you to lessen the burden of cancer for all Americans through greater understanding of cancer, its causes, and its cures.

Mr. Chairman, thank you for the opportunity to present on behalf of Charles R. Drew University of Medicine and Science.

PREPARED STATEMENT OF FIRST CANDLE/SUDDEN INFANT DEATH SYNDROME ALLIANCE

SUMMARY OF FISCAL YEAR 2003 RECOMMENDATIONS

—Continue to fund the third Sudden Infant Death Syndrome (SIDS) Five-Year Research Plan at NICHD, which focuses on research and educational opportunities on SIDS Stillbirth.
—Re-examine the third Five-Year Research Plan to determine the appropriateness of including research planning on stillbirth and miscarriage as components of the plan.
—Continue to fund the SIDS and Other Infant Death Program Support Center at the Maternal and Child Health Bureau, within the Health Resources and Services Administration.
—Fund 3 SIDS death scene protocol demonstration projects through the Centers for Disease Control and Prevention (CDC) in rural, urban, and suburban settings to provide a nation-wide protocol for dealing with SIDS death scenes.

Chairman Specter, thank you for again allowing First Candle/SIDS Alliance the opportunity to submit testimony to this Subcommittee and explain issues involving Sudden Infant Death Syndrome (SIDS), the importance of federal funding for SIDS

programs and research, and exciting changes currently transforming the SIDS Alliance. Mr. Chairman, we still need your help, commitment, and support to help solve the mystery that is SIDS and ensure healthy pregnancies and that every child lives.

Despite the fact that SIDS cases have been documented for years, organized scientific research into SIDS only began in the mid 1970's. In the three decades since, scientists are now beginning to make significant progress in unraveling this enigma of SIDS, which robs families of their infant children. As an example of this progress, we now know that in many SIDS related deaths there is an abnormality or underdevelopment in a region of an infant's brain, which is thought to control the heart and lung functions. In these cases, this irregularity may hamper normal respiratory activity. While this may not be the sole cause of SIDS, it may have contributed to a larger respiratory problem leading to death when combined with other circumstances.

As a direct result of SIDS research and the "Back to Sleep" educational and awareness campaign on infant sleep positioning, SIDS deaths have been reduced by 42 percent since 1992, leading to the greatest decline in infant mortality rates in over 20 years.

Despite this exceptional news, our research and educational campaign is far from finished. There are still more than 2,500 SIDS deaths in the United States each year and SIDS continues to be the number one cause of death for children between one month and one year of age. SIDS is a major component of the United States infant mortality rate. In spite of these facts, we still do not yet understand the causes of SIDS nor do we possess any guaranteed method for its prevention.

However, because of the decreasing rates of SIDS, in 2002, the SIDS Alliance moved to expand our mission and changed our name to First Candle/SIDS Alliance. First Candle/SIDS Alliance exists to promote infant health and survival during the prenatal period through two years of age. We will concentrate in this arena through advocacy, education, and research not only in the area of SIDS, but also branching out in the areas of Stillbirth and Miscarriage.

The primary federal agency responsible for conducting SIDS research and the "Back to Sleep" public awareness campaign is the National Institute of Child Health and Human Development (NICHD) at the National Institutes of Health (NIH). In addition to federal funding of SIDS research, there are other federal agencies involved in the SIDS effort. Since 1975, the Maternal and Child Health Bureau (MCHB) within the Health Resources and Services Administration (HRSA) has supported specific programs for SIDS bereavement services such as family counseling and for public and professional education about SIDS. The Centers for Disease Control and Prevention (CDC) has established a standardized death scene investigation protocol for SIDS incidents. Additionally an Interagency Panel on SIDS has been established, which includes: NIH, HRSA, CDC, Indian Health Services (HIS), Food and Drug Administration (FDA), U.S. Consumer Products Safety Commission, Department of Defense, Administration for Children and Families, and the Department of Justice to help coordinate all federally funded SIDS activities.

First/Candle SIDS Alliance is grateful for the Subcommittee's past support of SIDS activities, especially the support of NICHD. We urge you to again provide the additional funding necessary for the third year of the third Five-Year SIDS Research Plan to ensure that NICHD can continue to address critical SIDS research initiatives. Specifically the SIDS Alliance is supporting a funding increase to $29.8 billion or 10 percent for NIH overall, and a 10 percent increase for NICHD to $1.33 billion. We respectfully ask that the increases for NIH do not come at the expense of other Public Health Service agencies. Further research is essential to find the reasons for and means of preventing the tragedy of SIDS as well as providing research to understand the causes of Stillbirth and Miscarriage.

First Candle/SIDS Alliance urge the Subcommittee to support SIDS educational, awareness, and counseling activities that take place at the MCHB, and the death scene investigation protocol demonstration projects at the CDC. These programs are a vital companion to the research conducted at NICHD. Without prevention, awareness, counseling and standardized investigation procedures, competent scientific research does not translate into meaningful advances for SIDS victims and their families.

HIGHLIGHTS OF FEDERALLY FUNDED SIDS ACTIVITIES

National Institute of Child Health and Human Development (NICHD)

Childcare has become increasingly important in the social fabric of the United States, so have child care centers and homes. To address this issue the NICHD has initiated the "Back to Sleep Child Care Project," sending publications and other "Back to Sleep" materials to over 280,000 child care centers and licensed homes

throughout the United States. Response to these mailings has been overwhelming, resulting in a 20 percent increase in the volume of requests for Back to Sleep materials. 20 percent of all SIDS deaths occur in a childcare setting. First Candle/SIDS Alliance and NICHD, as well as other coalition partners such as the American Academy of Pediatrics (AAP), have joined in a collaborative initiative launched by MCHB. This initiative calls attention to this problem and works to further educate policy makers and day care providers regarding infant sleep positioning with the goal of further decline in the number of SIDS deaths every year.

Studies on the risk factors for SIDS among African American and American Indian populations conducted in collaboration with the CDC and the Indian Health Service have yielded valuable information for targeted interventions to reduce infant mortality in these communities. SIDS among minority populations continues to be a top priority for the NICHD. Surveys show that the proportion of African Americans placing their infants to sleep on their stomachs continues to decrease, however, African Americans are still twice as likely to place infants on their stomachs as compared to other populations. Discussion groups are underway in African American communities across the country to assess the "Back to Sleep" campaign message, and to improve message delivery. In addition, during fiscal year 2001, the NICHD established new initiatives on health disparities in minority populations. SIDS and related fetal and infant deaths are part of the initiatives targeted at eliminating health disparities in infant mortality.

A new component of the "Back to Sleep" campaign focusing on reducing SIDS among African American's was launched in late 1999. The goal is to develop and implement a community-based initiative. The National Black Child Development Institute (NBCDI) joined with the NICHD, the campaign sponsors, and several other organizations in the outreach initiative. A culturally appropriate resource kit, which includes a training guide, has been developed, and the first national training workshops have been held.

The mechanism of SIDS is still unknown; there are no clinical or biologic tests to identify a newborn at high risk of succumbing to SIDS; and more work is needed to increase the implementation of "Back to Sleep" among all caregivers and in communities with high rates of infant death. To address and focus its efforts on these challenges, the NICHD has developed and is implementing its third SIDS Research Five-Year Plan. The plan is divided into five parts: Introduction, Etiology/Pathogenesis, Prognostics and Diagnostics, Prevention, and Health Disparities. Because of our expanded mission, First Candle/SIDS Alliance is asking the Subcommittee to direct NICHD to review the third SIDS five-year plan to investigate the appropriateness and scientific viability of including Stillbirth and Miscarriage in current Five-Year Research Plan for SIDS.

Research initiatives in fiscal year 2004 include (1) continued research on mechanisms of pathogenesis through studies in animal models, postmortem tissue, and high-risk infants. This includes a prospective study to define a battery of physiologic and genetic markers that will predict SIDS and to determine whether SIDS is part of a larger family of autonomic nervous system disorders; (2) analysis of epidemiological and physiological data collected during the second five year research plan to improve our understanding of environmental and intrinsic risk factors; (3) a community-linked health disparities initiative to investigate related aspects of mortality from late fetal life through early childhood; (4) improve risk reduction and efficacy of "Back to Sleep" through continued research, monitoring, and outreach in at risk communities.

Maternal and Child Health Bureau (MCHB)

Recently, First Candle/SIDS Alliance has entered into a collaborative effort with MCHB to kickoff the "Healthy Child Care America Back to Sleep Campaign". This initiative builds on the success of the "Healthy Child Care America" and "Back to Sleep" campaigns to unite child care, health, and SIDS prevention partners across the country to reduce the number of SIDS-related deaths in child care settings.

The MCHB continues to support a number of SIDS and Other Infant Death related services and programs, including the following activities:

—National SIDS Resource Center, a major source of current information about SIDS.

—Maternal and Child Health Service Block Grant (MCH), which grants funds to states providing a range of services to SIDS families. Block grant funds support activities like: contact families immediately after death, discussion of autopsy results with the family, and support and counseling through the first year of bereavement. Unfortunately, in many jurisdictions across the country, funds for these services have been decreased or eliminated due to budgetary difficulties.

—Field training and curriculum to health care providers for case management of families who have experienced an infant death, and the development of model programs, particularly for the underserved and minorities. Demonstration grants have been established and are continuing in four states to target services for specific populations: California, Massachusetts, Missouri, and New York.
—National SIDS & Infant Death Program Support Center to address SIDS service issues at the federal level on an ongoing basis. First Candle/SIDS Alliance was chosen to run this center, which opened in 1999, and has experienced notable success. The support center is working to expand bereavement services to family members of those you experience stillbirth and miscarriage.

Centers for Disease Control and Prevention (CDC)

To develop a better statistical figure on SIDS cases, Congress recommended in 1993 the establishment of a standard death scene protocol to offset discrepancies on unexplained infant deaths between states. It was hoped that this protocol would be adopted by states not only for statistical measure, but to help avoid what can become awkward and emotionally charged misunderstandings at the death scene. In 1996, CDC published the protocol, and since that time several states have adopted the standard. It is First Candle/SIDS's Alliance long term goal to ensure that all states fully adopt and implement the protocol. To help realize this goal, First Candle/SIDS Alliance would like Congress to appropriate funds for CDC to heed Congress' recommendations for the past several years and implement the demonstration projects that follow these guidelines in several community settings nationwide. We recommend a demonstration project in each of the following, a rural community setting, an urban community setting, and a suburban community setting. We would also encourage CDC to implement a nationwide survey to measure how many locales have already implemented the protocol independently and to analyze the results thus far.

In conclusion, we are all too painfully aware that SIDS has historically been a mystery, leaving in its wake devastated families and bewildered physicians. Not only have there been no answers on the cause of SIDS, but there have been no answers on how to effectively prevent its occurrence. Today we are beginning to find some of the answers on cause and prevention, and therefore reduce the risk of SIDS. Because of the "unknown", however, babies are still vulnerable even when parents and care givers take the cautionary steps to prevent SIDS deaths. This tragedy will continue if research efforts are stalled or halted, especially when we are at the point where so much progress has been made. Now is the time for a re-energized effort against this tragic syndrome.

On behalf of the thousands of families who have been devastated by the loss of a baby to SIDS, and the millions of concerned and frightened parents, we ask for your support, and thank you again for allowing us to submit this testimony. If you have any questions, please do not hesitate to contact us.

FIRST CANDLE/SUDDEN INFANT DEATH SYNDROME ALLIANCE

First Candle/SIDS Alliance is an organization of parents and friends of SIDS victims along with medical, business, and civic groups who are concerned about the health our this nation's children. The Alliance is engaged in ongoing efforts to expand its scientific program, strengthen services for families, and provide public education and advocacy opportunities. An important goal is to improve community understanding and elevate SIDS to the level of societal concern appropriate to one of our nation's major causes of infant mortality.

PREPARED STATEMENT OF THE CROHN'S AND COLITIS FOUNDATION OF AMERICA

SUMMARY OF FISCAL YEAR 2004 RECOMMENDATIONS

—A 10 PERCENT INCREASE FOR THE NATIONAL INSTITUTE OF DIABETES, AND DIGESTIVE AND KIDNEY DISEASES, AND THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES AND A CORRESPONDING INCREASE FOR INFLAMMATORY BOWEL DISEASE RESEARCH AT BOTH INSTITUTES.
—$1 MILLION FOR THE NATIONAL INFLAMMATORY BOWEL DISEASE EPIDEMIOLOGICAL PROGRAM AT THE CENTERS FOR DISEASE CONTROL AND PREVENTION.
—$25 MILLION FOR CDC's NATIONAL COLORECTAL CANCER SCREENING AWARENESS PROGRAM.

INTRODUCTION

Mr. Chairman, thank you very much for the opportunity to present the views of the Crohn's & Colitis Foundation of America (CCFA). I am Rodger DeRose, President and Chief Executive Officer of CCFA and I am honored to represent the people of this country who suffer from Crohn's disease and ulcerative colitis.

Crohn's disease and ulcerative colitis are chronic disorders of the gastrointestinal tract which represent a leading cause of morbidity from digestive illness. Because they behave similarly, these disorders are collectively known as inflammatory bowel disease (IBD). IBD can cause severe diarrhea, abdominal pain, fever, and rectal bleeding. Moreover, IBD related complications can include; arthritis, osteoporosis, anemia, liver disease, and colon cancer. Crohn's disease and ulcerative colitis are not fatal, but they can be devastating. We do not know their cause, and we have no cure.

CCFA is a non-profit, voluntary organization dedicated to finding a cure for Crohn's disease and ulcerative colitis. Throughout its 36-year history, CCFA has sponsored basic and clinical research of the highest quality. The Foundation also offers a wide range of educational programs for patients and healthcare professionals, and provides support services to assist people in coping with these chronic intestinal diseases.

We are very grateful Mr. Chairman, for your support of IBD research and epidemiology programs in the Fiscal Year 2003 Labor-HHS bill. Furthermore, we applaud the leading role that you played in the successful effort to double the NIH budget and your recent amendment to the budget resolution providing for an increase in NIH spending in fiscal year 2004.

RECOMMENDATIONS FOR FISCAL YEAR 2004

National Institutes of Health

CCFA has developed highly successful research partnerships with the NIH. We are particularly proud of our longstanding collaborations with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) which sponsors the majority of IBD research at NIH, and the National Institute of Allergy and Infectious Diseases (NIAID).

In 2001, a team of investigators from NIDDK, CCFA, and the private industry announced that they had identified the first gene for Crohn's disease. This historic breakthrough opens up exciting new pathways of research focused on the development of improved therapies for Crohn's disease patients. The research which led to the discovery of the gene would not have been possible without the strong support that Congress has provided to the NIDDK in recent years.

Some of the most promising IBD research supported by the NIH has focused on translating findings from studies conducted on animal models to humans with IBD. These animal models have enabled researchers to form the current hypothesis that Crohn's disease and ulcerative colitis are caused by a malfunctioning immune system, wherein components of the patient's immune system overreact to normal intestinal bacteria. We know that people are susceptible to this malfunction because of their genetic makeup but further research is necessary to determine which bacteria are responsible, how these bacteria interact with the intestine's immune system, and which immune system components are involved.

Mr. Chairman, IBD patients and their families are pinning their hopes for a better life on medical advancements made through NIH sponsored research. For this reason, CCFA strongly supports the goal of the doubling the NIH budget and recommends a 10 percent increase for NIDDK, NIAID, and NIH overall in fiscal year 2004. Moreover, CCFA encourages the subcommittee to increase IBD research funding within NIDDK and NIAID at the same rate as NIH overall.

CENTERS FOR DISEASE CONTROL AND PREVENTION

IBD Epidemiology Program

CCFA estimates that "up to one million" people in the United States suffer from IBD. Unfortunately, we do not have an exact number; due to the complicated nature of those diseases, patients may remain undiagnosed or misdiagnosed for several years. One of CCFA's main public policy objectives is to establish a nationwide IBD epidemiological program in partnership with the Centers for Disease Control and Prevention. This much-needed program will further our understanding of both the prevalence of IBD in the United States, and the demographic characteristics of this unique patient population.

The cultivation of patient demographic information is critically important to our biomedical research efforts given that environmental factors are believed to play a

major role in the development and progression of IBD. If we are able to generate an accurate analysis of the geographic makeup of the IBD patient population, it will provide us with invaluable clues about the potential causes of IBD.

As a result, CCFA entered into a partnership last year with the CDC to establish an IBD epidemiology program. Specifically, CCFA has funded a grant that CDC submitted to the Foundation to initiate this important study. We greatly appreciate your support of this collaboration as outlined in the Committee's fiscal year 2003 Labor-HHS bill. We are looking forward to reviewing a report on the progress CDC is making in this area, as requested by the Committee. Moreover, we are pleased that the Committee has strongly encouraged CDC to provide financial support for this study now that it has been initiated with funds from our non-profit organization.

For fiscal year 2004, we are requesting that the Committee provide CDC with a specific appropriation of $1 million to continue this important initiative.

Colorectal Cancer Prevention

Finally, Mr. Chairman, in addition to coping with either Crohn's disease or ulcerative colitis, many IBD patients are at high risk for developing colorectal cancer. As you may know, colorectal cancer is the third most commonly diagnosed cancer for both men and women in the United States and the second leading cause of cancer-related deaths. Because people who have suffered from IBD for more than eight years are susceptible to this disease, CCFA has a long history of actively promoting the benefits of colorectal cancer screening.

Although colorectal cancer is almost entirely curable when detected early, studies have shown a tremendous need to: (1) inform the public about the availability and advisability of screening and (2) educate healthcare providers about screening guidelines. CDC's National Colorectal Cancer Roundtable is actively working to address these challenges by partnering with organizations like CCFA to implement a national public awareness campaign emphasizing the importance of screening and early detection. Moreover, CDC's "Screen for Life" awareness campaign is actively promoting the importance of colorectal cancer screening via television, radio and print media. CCFA encourages the subcommittee to provide CDC with $25 million in fiscal year 2004 to support its colorectal cancer prevention activities.

Once again, Mr. Chairman, thank you for the opportunity to present the views of Crohn's and Colitis Foundation of America. We look forward to continuing to work with you on these important issues.

PREPARED STATEMENT OF THE DYSTONIA MEDICAL RESEARCH FOUNDATION

SUMMARY OF FISCAL YEAR 2004 RECOMMENDATIONS

—Provide increased funding for the National Institute of Health at 10 percent for fiscal year 2004. Increase funding for the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Deafness and other Communication Disorders (NIDCD), and the National Eye Institute (NEI) by 10 percent.

Fiscal year 2004 recommendations for NIH

[In billions of dollars]

NIH	29.800
NINDS	1.610
NIDCD	0.409
NEI	0.700

—Continue to accelerate funding for extramural dystonia research at NINDS.
—Provide funding for NINDS to conduct an epidemiological study and to increase public and professional awareness of dystonia.
—Continue to expand NIDCD's intramural and extramural research on dysphonia.
—Continue to expand NEI's intramural and extramural research on dystonia.

Chairman Specter, thank you for again allowing me the opportunity to submit testimony to the Subcommittee on behalf of the Dystonia Medical Research Foundation (DMRF). I want to take this opportunity to describe for the Subcommittee how dystonia has affected the lives of many Americans and to provide for you our recommendations for fiscal year 2004 federal funding with regards to dystonia research.

My name is Rosalie Lewis, I am currently president of the Dystonia Medical Research Foundation (DMRF). Dystonia is a neurological disorder characterized by

powerful and painful involuntary muscle spasms that causes the body to twist, repetitive jerking movements, and sustained postural deformities. There are several different variations of dystonia, including: focal dystonias which affect specific parts of the body, such as the arms, legs, neck, jaw, eyes, vocal cords; and generalized dystonia, affecting many parts of the body at the same time. Some forms of dystonia are genetic and others are caused by injury or illness. Dystonia does not affect a person's consciousness or intellect, but is a chronic and progressive movement disorder for which, at this time, there is no known cure. The Foundation estimates that some form of dystonia affects about 300,000 people in North America.

I have a very personal connection with this disorder because I am the mother of four sons, three of whom suffer from the complications of dystonia, and a fourth who is a carrier of the DYT1 gene which is responsible for generalized early onset childhood dystonia. Even though there is no known cure for dystonia, there are treatments to lessen the severity of the symptoms of the disease such as oral medications, botulinum toxin injections, and in some cases surgery. Having increased access to these medical therapies is becoming an increasing larger issue for the community as a whole.

In the past few decades, dystonia researchers have made several exciting scientific advancements and have been able to rapidly turn laboratory and clinical research into diagnostic examinations and treatment procedures, directly benefiting those affected. Genetics, in particular, is opening up a new understanding into the cause and pathophysiology of the disorder. Thus far, 13 dystonia related genes or gene loci have been identified. In 1997, the DYT1 gene for childhood early onset dystonia was identified, and we now have a genetic test available to confirm diagnosis of this particular type of dystonia. Most recently, in 2002, the gene for myoclonus dystonia was identified. However the community is still without a diagnostic test and misdiagnosis still occurs too frequently.

Deep brain stimulation is a surgical procedure that was originally developed to treat Parkinson's disease but is now being applied to severe cases of dystonia. Deep brain stimulation has drastically improved the lives of dozens of dystonia patients during the past few years. Individuals who were previously bedridden by muscle spasms and pain are able to walk without assistance, to speak clearly, to dress themselves, to get a driver's license, to date, to travel, and to live the life of an able-bodied person. Deep brain stimulation is currently used primarily to treat severe cases of generalized dystonia but its promising role in treating focal dystonias is being explored. Surgical interventions are a crucial and active area of dystonia research.

RESEARCH, AWARENESS, AND SUPPORT

Now is an exciting time to be involved in dystonia research and awareness. Researchers are becoming more interested in movement disorders and dystonia at the National Institutes of Health (NIH), and research is yielding promising clues for better understanding and management of this disorder.

One way the Dystonia Medical Research Foundation has advocated for more research on dystonia, is by funding "seed" grants to researchers. Thus far, the Dystonia Foundation has funded over 370 grants, and 5 fellowships, totaling more than $18 million. Due to our advocacy there are a growing number of talented researchers dedicated to understanding the biochemistry of dystonia, genetic causes, new therapeutics and the necessity of an epidemiology study.

Another primary goal of the Dystonia Foundation is education of both lay and medical audiences. The Foundation conducts regular medical workshops and patient symposiums to present, discuss, and disseminate comprehensive medical and research data on dystonia. In January 2001, NINDS co-sponsored a genetics and animal models meeting, designed to involve not only prominent researchers but inviting junior investigators to participate in the discussions. Additionally, in October 1996, the NIH was one of our co-sponsors for an international medical symposium, which featured 60 papers on dystonia and 125 representatives from 24 countries. The Young Investigators Award Program and the Residency Program are in place to entice emerging medical professionals into the field of dystonia research and cultivate future dystonia experts.

Since 1995, over 3,000 educational medical videos have been distributed to hospitals, medical and nursing schools, and at medical conventions. In addition to medical and coping publications, we have a children's video to educate families and increase public awareness of this devastating disorder in younger populations. Media awareness is conducted throughout the year, and especially during Dystonia Awareness Week, observed nationwide from October 14 through 20. Local volunteers have been successful in securing news stories on dystonia in local venues as well as na-

tional media shows such as *Good Morning America, The Oprah Winfrey Show, and Maury Povich.* Through his friendship with the mother of a dystonia patient, screen star Kirk Cameron has taken an interest in promoting dystonia awareness, and the Dystonia Foundation is in the process of investigating the possibility of a public service announcement and several appearances at fundraising events.

The Dystonia Foundation has over 200 chapters, support groups, and area contacts across North America. In addition, there are 15 international chairpersons whose mission is to promote awareness, children's advocacy, development, extension, Internet resources, leadership, medical education, and symposiums. Furthermore, patient symposiums are held internationally and regionally to provide the latest medical and coping information to dystonia patients and others interested in the disorder. In 2000, we held over eight regional symposiums reaching approximately 2,000 affected families. Eight more regional symposiums are scheduled throughout 2003 and 2004.

DYSTONIA AND THE NATIONAL INSTITUTES OF HEALTH

The Dystonia Medical Research Foundation recommends an increase to $29.8 billion or 10 percent for NIH overall, and a 10 percent increase for NINDS, NIDCD and NEI or: $1.61 billion, $409 million, and $700 million respectively. Now that the NIH doubling is complete, NIH still must have the adequate resources to continue the research it has begun during the period of the doubling. We at DMRF request that this increase for NIH does not come at the expense of other Public Health Service agencies. 2002 was a banner year in the field of dystonia research with the release in August of the NIH Program Announcement: *Studies in the Causes and Mechanisms of Dystonia.* This program announcement is a historic collaboration for research on behalf of the dystonia community throughout the NIH and it serves as an example of the success of the NIH doubling of funding to make this possible. If NIH is not adequately funded then many of the grant proposals associated with the program announcement could go unfunded hindering the scientific progress we in the dystonia community have made in the past few years.

Dystonia is the third most common movement disorder after Parkinson's Disease and tremor, and effects many times more people than better known disorders such as Huntington's Disease, muscular dystrophy and ALS or Lou Gehrig's Disease. We ask that NINDS fund dystonia-specific extramural research at the same level that it supports research for other neurological movement disorders.

We also urge the Subcommittee to recommend that NINDS provide the necessary funding for additional extramural research and a large-scale dystonia epidemiological study. There is also an imperative need for NINDS to increase its efforts to educate the public and medical community about dystonia through co-sponsorship of workshops and seminars. We also encourage the Subcommittee to support NIDCD in its efforts to revamp its strategic planning process by implementing a Strategic Planning Group which will help NIDCD as they: consider applications for high program priority; develop program announcements and requests for applications; and develop new research areas in the Intramural Research Program.

The ultimate goal of the Dystonia Foundation is a cure for dystonia. Until that goal is realized, we are hungry for knowledge about the nature of dystonia and for more effective treatments with fewer side effects. We have amassed many exceptional and diligent researchers; who are committed to our goal, and our top priority is funding their very important research. But the Foundation cannot do it alone. We need federal support though NIH, NINDS, NIDCD and NEI to continue to fund quality scientific research and eliminate this debilitating disease.

Combine the thwarting of scientific progress with the decreased access to therapies and all the progress of the last few years could be wiped away. We ask that you aggressively support medical research, specifically for movement disorders and brain research. By doing so, you are doing a tremendous service for my family and myself and to the hundreds of thousands of people and families affected by dystonia.

Thank you very much.

THE DYSTONIA MEDICAL RESEARCH FOUNDATION

The Dystonia Medical Research Foundation was founded 25 years ago and has been a membership-driven organization since 1993. Since its inception, the goals of the Foundation have remained the same: to advance research for more effective treatments of dystonia and ultimately a cure; to promote awareness and education; and support the needs and well being of affected individuals and their families.

PREPARED STATEMENT OF THE MEDICAL LIBRARY ASSOCIATION AND THE ASSOCIATION OF ACADEMIC HEALTH SCIENCES LIBRARIES

SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2004

(1) A 10 PERCENT INCREASE FOR THE NATIONAL LIBRARY OF MEDICINE AT THE NATIONAL INSTITUTES OF HEALTH AND SUPPORT FOR NLM'S URGENT FACILITY CONSTRUCTION NEEDS.

(2) CONTINUED SUPPORT FOR THE MEDICAL LIBRARY COMMUNITY'S ROLE IN NLM'S OUTREACH, TELEMEDICINE, AND MEDICAL INFORMATICS PROGRAMS.

Mr. Chairman, thank you for the opportunity to submit testimony on behalf of the Medical Library Association (MLA) and the Association of Academic Health Sciences Libraries (AAHSL) regarding the fiscal year 2004 budget for the National Library of Medicine. I am Logan Ludwig, Associate Dean for Library and Telehealth Services at Loyola University Strich School of Medicine in Maywood, Illinois.

Established in 1898, MLA is a nonprofit, educational organization of more than 1,100 institutions and 3,600 individual members in the health sciences information field, committed to educating health information professionals, supporting health information research, promoting access to the world's health sciences information, and working to ensure that the best health information is available to all.

AAHSL is comprised of the directors of libraries of 142 accredited U.S. and Canadian medical schools belonging to the Association of American Medical Colleges. Together, MLA and AAHSL address health information issues and legislative matters of importance to the medical community through a joint task force.

Mr. Chairman, the National Library of Medicine, on the campus of the National Institutes of Health in Bethesda, Maryland, is the world's largest medical library. The Library collects materials in all areas of biomedicine and health care, as well as works on biomedical aspects of technology, the humanities, and the physical, life, and social sciences. The collections stand at 5.8 million items—books, journals, technical reports, manuscripts, microfilms, photographs and images. Housed within the library is one of the world's finest medical history collections of old and rare medical works. The Library's collection may be accessed in the reading room or requested on interlibrary loan. NLM is a national resource for all U.S. health science libraries through a National Network of Libraries of Medicine. Increasingly, it is becoming an international resource for world-wide research collaboration.

On behalf of the medical library community, I would like to thank the subcommittee for its leadership in securing a 12 percent increase for NLM in fiscal year 2003. With respect to the Library's budget for the coming fiscal year, I would like to touch briefly on four issues; (1) the growing demand for NLM's basic services; (2) NLM's outreach and education services; (3) NLM's telemedicine and informatics activities; and (4) NLM's facility needs.

THE GROWING DEMAND FOR NLM'S BASIC SERVICES

Mr. Chairman, it is a tribute to NLM that the demand for its services continues to steadily increase each year. An average of 500 million Internet searches are performed annually on NLM's MEDLINE database, which provides access to the world's most up-to-date health care information. MEDLINEplus, NLM's extensive electronic information resource for the general public, is viewed approximately 200 million times a year. This activity dwarfs previous usage of NLM's bibliographic services, whether electronic or print. Moreover, researchers, scholars, librarians, physicians, healthcare providers from around the world, and the general public rely heavily on NLM and its National Network of Libraries of Medicine to deliver health care information everyday that is necessary to improve the quality of our nation's healthcare system.

NLM also plays a critical role in maintaining the integrity of the world's largest collection of medical books and journals. Increasingly, this current and historical information is in digital form. This has fundamentally changed how the library operates—how and what it collects, how it preserves information, and how it disseminates biomedical knowledge. NLM, as a national library responsible for preserving the scholarly record of biomedicine, is developing a strategy for selecting, organizing, and ensuring permanent access to digital information. Regardless of the format in which the materials are received, ensuring their availability for future generations remains the highest priority of the Library.

Mr. Chairman, simply stated, NLM is a national treasure. I can tell you that without NLM our nation's medical libraries would be unable to provide the quality information services that our nation's healthcare providers, educators, researchers and patients have come to expect.

Recognizing the invaluable role that NLM plays in our health care delivery system, the Medical Library Association and the Association of Academic Health Sciences Libraries join with the Ad Hoc Group for Medical Research Funding in recommending a 10 percent increase for NLM and NIH overall in fiscal year 2004.

OUTREACH AND EDUCATION

NLM's outreach programs are of particular interest to both MLA and AAHSL. These activities, designed to educate medical librarians, health care professionals and the general public about NLM's services, are an essential part of the Library's mission.

The Library has taken a leadership role in promoting educational outreach aimed at public libraries, secondary schools, senior centers and other consumer-based settings. NLM's emphasis on outreach to underserved populations assists the effort to reduce health disparities among large sections of the American public. We were pleased that the Committee again last year recognized the need for NLM to coordinate its outreach activities with the medical library community.

PubMed Central

The medical library community also applauds NLM for its leadership in establishing PubMed Central, an online repository for life science articles. Introduced in 2000, PubMed Central was created by NLM's National Center for Biotechnology Information and evolved from an electronic publishing concept proposed by former NIH Director Dr. Harold Varmus. The site houses articles from some 100 journals including the *Proceedings of the National Academy of Sciences and Molecular Biology of the Cell.*

The medical library community believes that health sciences librarians should continue to play a key role in further development of PubMed Central and we are pleased that medical librarians are members of the NLM PubMed Central Advisory Committee. Because of the high level of expertise health information specialists have in the organization, collection and dissemination of medical literature, we believe our community can assist NLM with issues related to copyright, fair use, and information classification on the PubMed Central site. We look forward to continuing our collaboration with the Library as this exciting project continues to evolve this year.

MEDLINEplus

NLM estimates that the public conducts 30 percent of all MEDLINE searching. MEDLINEplus [http://www.nlm.nih.gov/medlineplus/], a source of authoritative, full-text health information resources from the NIH institutes and a variety of non-Federal sources, has grown tremendously in its coverage of health and its usage by the public. In January 2003, two million unique users searched more than 600 "health topics" that contain detailed consumer-focused information on various diseases and health conditions. Recent additions to MEDLINEplus include illustrated interactive patient tutorials, a daily news feed from the public media on health-related topics, and the NIHSeniorHealth site [http://nihseniorhealth.gov/], a collaborative project between NLM and the National Institute on Aging.

Clinical Trials

Mr. Chairman, I also want to comment on another relatively new service offered by NLM—its clinical trials database [http://www.clinicaltrials.gov]. This listing of more than 7,000 federal and privately funded trials for serious or life-threatening diseases was launched in February of 2000 and currently logs more than 2 million page hits per month. The clinical trials database is a free and invaluable resource to patients and families interested in participating in cutting edge treatments for serious illnesses. The medical library community congratulates NLM for its leadership in creating ClinicalTrials.gov and looks forward to assisting the Library in advancing this important initiative.

Mr. Chairman, we applaud the success of NLM's outreach initiatives and look forward to continuing our work with the Library again in fiscal year 2004 on these important programs.

TELEMEDICINE AND MEDICAL INFORMATICS

Mr. Chairman, telemedicine continues to hold great promise for dramatically increasing the delivery of health care to underserved communities across the country and throughout the world. NLM has sponsored over 50 innovative telemedicine related projects in recent years, including 21 multi-year projects in various rural and urban medically underserved communities. These sites serve as models for:

—Evaluating the impact of telemedicine on cost, quality, and access to health care;
—Assessing various approaches to ensuring the confidentiality of health data transmitted via electronic networks; and
—Testing emerging health data standards.

It is clear that telemedicine and medical informatics program such as the Visible Human Project [http://www.nlm.nih.gov/research/visible/visible__human.html]—male and female data sets consisting of MRI, CT, and photographic cryosection images totaling 50 gigabytes and licenses to scientists at more than 1,700 institutions around the world—will play a major role in the delivery of health care and research in the 21st Century.

We are pleased that NCM has begun a new program to support informatics research that addresses information management problems relevant to disaster management. Medical librarians and health information specialists have an important role to play in supporting these cutting edge technologies, and we encourage Congress and NLM to continue their strong support of telemedicine and other medical informatics initiatives.

NLM'S FACILITY NEEDS

Mr. Chairman, over the past two decades NLM has assumed several new responsibilities, particularly in the areas of biotechnology, health services research, high performance computing, and consumer health. As a result, the Library has had tremendous growth in its basic functions related to the acquisition, organization, and preservation of an ever-expanding collection of biomedical literature.

This increase in the volume of biomedical information as well as expansion of personnel (NLM currently houses over 1,100 people in a facility built to accommodate 650) has resulted in a serious shortage of space at the Library. In addition, NLM's National Center for Biotechnology Information [http://www.ncbi.nlm.nih.gov] builds sophisticated data management tools for processing and analyzing enormous amounts of genetic information critical to advancing the Human Genome Project.

In order for NLM to continue its mission as the world's premier biomedical library, a new facility is urgently needed. The NLM Board of Regents has assigned the highest priority to supporting the acquisition of a new facility. The medical library community is pleased that Congress last year appropriated the necessary architectural and engineering funds for facility expansion at NLM.

We encourage the subcommittee to continue to provide the resources necessary to acquire a new facility and to support the Library's health information programs.

Mr. Chairman, thank you once again for the opportunity to present the views of the medical library community.

PREPARED STATEMENT OF THE AMERICAN PSYCHOLOGICAL SOCIETY

SUMMARY OF RECOMMENDATIONS

—As a member of the Ad Hoc Group for Medical Research Funding, APS recommends $30 billion for NIH in fiscal year 2004.
—APS requests Committee support for increased behavioral and social science research and training at NIH in order to: better meet the Nation's health needs, many of which are behavioral in nature; realize the exciting scientific opportunities in behavioral and social science research, and; accommodate the changing nature of science, in which new fields and new frontiers of inquiry are rapidly emerging.
—Committee support is requested for specific behavioral science activities at a number of individual institutes. This testimony provides examples to illustrate the exciting and important behavioral and social science work being supported at NIH.

Mr. Chairman, Members of the Committee: On behalf of our members, I want to thank the Committee for your leadership in the bipartisan effort to double NIH budget. As a member of the Ad Hoc Group for Medical Research Funding, the American Psychological Society recommends $30 billion for NIH in fiscal year 2004. After the historic doubling of NIH budget, thanks to the efforts of Congress and both the Clinton and Bush administrations, the rationale for these aggressive increases remains as compelling today as it was in fiscal year 1999, the year that you and your colleagues in Congress embarked on this path. NIH has experienced a period of unparalleled growth in the past 5 years, and the progress achieved as a result of research funded by NIH will lead us into a new era of discovery and innovation.

Within NIH budget, my testimony today focuses on the behavioral and social science research activities of NIH.

OVERVIEW: BASIC AND APPLIED PSYCHOLOGICAL RESEARCH RELATED TO HEALTH

The effects of behavior on health are indisputable.—Many leading health conditions—heart disease, lung disease, diabetes, developmental disabilities, brain injury, AIDS, and so many more—are behavioral in origin. Consider, for example, the devastating health consequences of smoking, drinking, taking drugs, engaging in risky sexual behaviors. None of these conditions can be fully understood without an awareness of the behavioral and psychological factors involved in causing, treating and preventing them.

APS members include thousands of scientists who, with NIH support, conduct basic, applied, and clinical research related to physical and mental health at our Nation's leading universities and colleges. Virtually every institute at NIH supports some amount of psychological science. Examples include: The connections between the brain and behavior; research into how children grow and develop; management of debilitating chronic conditions such as diabetes and arthritis as well as mental disorders; and the behavioral aspects of smoking and drug and alcohol abuse, so that science may find ways for people to escape addiction.

The new director of NIH, Dr. Elias Zerhouni, has expressed strong support for behavioral science at NIH, and sees this research as critical to our nation's health. "We are aware of the challenge in social and behavioral science. It's going to be front and center," he has stated. He went on to add, "The bill for the nation will be unbearable in health and social costs without a recognition of the role of behavior."

Twenty-four of the 27 institutes at NIH fund behavioral science research, and seven institutes commit over $100 million to this enterprise. Six institutes commit over 20 percent of their resources to behavioral science research. That places these pursuits squarely at the forefront of the most pressing health issues facing this Congress, this Administration, and this Nation. We ask that you continue to help make behavioral research more of a priority at NIH, both by providing maximum funding for those institutes where behavioral science is a core activity, and by encouraging NIH to advance a model of health that includes behavior in deciding its scientific priorities.

BEHAVIORAL SCIENCE RESEARCH TRAINING: A GUARANTEED INVESTMENT

The outcomes of science are unpredictable.—Yet there is one aspect of science where the time and money invested is guaranteed to pay off: the training of our future scientists. We know that if we provide support now for a young investigator, we will have a well-trained, highly-qualified scientist as a result. This is a serious issue in behavioral science at NIH, where the demand for behavioral science investigators at NCI, NIMH, and other institutes outpaces the current supply of behavioral science researchers. In order to meet the future needs of research in health and behavior, NIH must have a comprehensive training strategy in place today, one that focuses on training young investigators in the core disciplines of behavioral and social science research as well as in multidisciplinary perspectives.

The National Academy of Sciences is currently conducting its congressionally authorized study of research personnel needs with regard to the National Research Service Awards. In recent years, NIH has chosen to only implement the recommendations of NAS selectively, if at all. NAS produces unbiased, highly analytical reports, and they should receive more attention from all of the NIH institutes. This Committee has expressed interest in this study in the past. We hope that this committee will follow theses developments closely, and take an active role in the enforcement of these recommendations.

We ask the Committee to support the development, in consultation with the relevant scientific community, of a comprehensive training strategy for behavioral and social science research at NIH. This strategy should include all training mechanisms, and should be balanced between interdisciplinary research and traditional core disciplines in the behavioral sciences.

I would now like to turn my attention to the behavioral science research that is taking place at the individual institutes.

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

Strengthening Clinical Science.—Under the leadership of its new director Dr. Thomas Insel, NIMH is working with the Academy of Psychological Clinical Science to explore the development of training models for clinical science in psychology. The goal is to establish training for clinical scientists who will go on to create new ways

to diagnose, measure and treat mental disorders, and new ways to evaluate how those treatments translate from the lab to the real world. We ask the Committee to support the efforts of NIMH as the institutes takes this very complex first step in the on-going fight against mental illness.

Basic Behavioral Research at NIMH.—NIMH is to be commended for promoting the transfer of knowledge into application. At the same time, basic behavioral research at NIMH must continue to receive the same strong support it traditionally receives there. This is crucial, as NIMH is a de facto source of basic behavioral knowledge that is tapped by many other institutes. Until other institutes begin to support larger amounts of basic behavioral science research connected to their respective missions, it is essential that NIMH's programs of research into behavioral phenomena such as cognition, emotion, psychopathology, perception, development, and others continues to flourish. We ask the Committee to encourage NIMH's continued efforts to strengthen the ties between basic and clinical behavioral research, and to encourage NIMH's basic behavioral science portfolio in order to ensure continued progress in our understanding of the causes, treatment, and prevention of mental illness and the promotion of mental health.

Adherence and Behavior Change.—NIMH supports studies of factors that influence decisions about adopting and adhering to treatment and prevention interventions, including individual personality or disease-related factors and type of treatment, as well as factors that may enhance or interfere with adherence to prevention, treatment, or rehabilitative regimens. This research is critical to increasing the effectiveness of vaccines, drug therapies, smoking and substance abuse cessation and relapse prevention programs, and other advances in public health treatment and prevention.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

NIGMS is the only National Institute specifically mandated to support research not targeted to specific diseases or disorders. That legislative mandate also extends to behavioral science research. Unfortunately, NIGMS does not now support behavioral science research or training. This is an enormous oversight, given the wide range of fundamental behavioral topics with relevance to a variety of diseases and health conditions. Congress addressed this issue for the past four years in the reports on the fiscal year 2000, fiscal year 2001, fiscal year 2002, and fiscal year 2003 appropriations for NIH. Specifically, this Committee said: "The Committee is concerned that NIGMS does not support behavioral science research training. As the only Institute mandated to support research not targeted to specific diseases or disorders, there is a range of basic behavioral research and training that NIGMS could be supporting. The Committee urges NIGMS, in consultation with the Office of Behavioral and Social Sciences, to develop a plan for pursuing the most promising research topics in this area."

The institute's response in their fiscal year 2003 budget justification was inadequate. "The Institute's research training programs mirror the areas of science that fall within the mission of the National Institute of General Medical Sciences (NIGMS). Except for a few fields of inquiry, behavioral studies largely fall outside of the Institute's research mission, and are instead deemed to be within the missions of other institutes at the National Institutes of Health. " NIGMS is mistaken. Their research mission encompasses "general or basic medical sciences and related natural or behavioral sciences [emphasis added] which have significance for two or more other national research institutes" (TITLE 42, CHAPTER 6A, SUBCHAPTER III, Part C, subpart 11, Sec. 285k)

Basic behavioral research in addiction (significance for NIDA, NIAAA, NCI and NHLBI), obesity (significance for NIDDK, NHLBI, and NICHD) and neuroscience (significance for NIMH, NINDS, and NHGRI) just to name a few, are all within the NIGMS mission. Once again, we ask the Committee to direct NIGMS to develop a plan for establishing a basic behavioral science research program at NIGMS.

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

NIDA's National Prevention Research Initiative.—NIDA's new Prevention Research Initiative integrates basic science with prevention research. NIDA-supported investigators will draw on basic behavioral, cognitive, developmental, social and neurobiological research to inform the development of innovative and novel prevention interventions. NIDA will focus on preventing the initiation of drug abuse by better understanding basic cognitive processes, such as the decision to use a drug. This basic research component is just one of three components (along with establishment of transdisciplinary prevention centers and community multi-site prevention trials) that NIDA will use to enhance national prevention efforts. Understanding be-

havior will not only aid in the development of prevention strategies, it will also aid in the development of new therapies for those addicted to drugs.

NIDA Clinical Trials Network (CTN).—To date, the efficacy of new treatments for drug addiction has been demonstrated primarily in specialized research settings, with somewhat restricted patient populations. To address this problem, NIDA has established the National Drug Abuse Treatment Clinical Trials Network (CTN). The mission of the CTN is to conduct studies of behavioral, pharmacological, and integrated behavioral and pharmacological treatment interventions of therapeutic effect in rigorous, multi-site clinical trials to determine effectiveness across a broad range of community-based treatment settings and diversified patient populations; and then transfer the research results to physicians, providers, and their patients to improve the quality of drug abuse treatment throughout the country using science as the vehicle. There are currently 17 networks in place, up form 5 in 1999. We ask this Committee to increase NIDA's budget in proportion to the overall increase at NIH in order to reduce the health, social and economic burden resulting from drug abuse and addiction in this Nation.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

NIAAA has broadened its behavioral science portfolio in order to understand the underlying psychological and cognitive processes that lead people to drink, and the impact of chronic alcohol abuse on those processes. As one example, NIAAA convened a workshop of national experts on social identification and alcohol research to examine ways that group peer pressure and group norms concerning drinking influence drinking. The Institute also convened a group of experts in cognitive research to explore the effects of alcohol abuse on memory, decision-making, cognitive development to begin looking at issues of cognitive rehabilitation.

Advancing Behavioral Therapies for Alcoholism Behavioral, non-pharmacological therapies currently are the most widely used method of treating alcohol dependence and alcohol abuse. To advance the effectiveness of behavioral therapies, NIAAA is examining approaches to improving clinicians' abilities to engage and retain adults and adolescents in treatment. NIAAA plans to expand research on the mechanisms of action of successful behavioral therapies, behavioral therapies for alcohol-abusing patients who have psychiatric disorders, which significantly complicates therapeutic interventions, and combinations of new medications with behavioral therapies to sustain recovery. We ask this Committee to increase NIAAA's budget in proportion to the overall increase at NIH in order to reduce the health, social and economic burden resulting from alcohol abuse and addiction.

NATIONAL CANCER INSTITUTE (NCI)

Having already established itself as a leader among NIH Institutes in many fields of research, NCI has made enormous advances in the behavioral sciences.

NCI's Behavioral Research Program.—NCI's comprehensive behavioral science research program ranges from basic behavioral science to research on the development, testing and dissemination of disease prevention and health promotion interventions in areas such as tobacco use, diet, and even sun protection. Focusing on transdisciplinary and collaborative research, NCI's Behavioral Program has expanded to five branches, including a basic biobehavioral research branch, a health communication and informatics research branch, and the tobacco control research branch. The transdisciplinary research conducted by NCI is an example of the new path for science, as disciplines are only made stronger when complimented by others. With every new discovery that arises, we see more and more that no branch of science is complete if it stands alone.

Health Communications.—Recognizing the central role of effective communication in addressing issues of health and behavior, NCI has also undertaken a major effort to develop science-based communications strategies for disseminating information and persuasive messages about cancer prevention and treatment to the public. Researchers are exploring innovative strategies for communicating cancer information to diverse populations, looking at various communication approaches such as message tailoring and framing with application in multiple communication channels. These messages draw from a foundation of basic behavioral and social science research into such issues as how people learn and remember health information, how they perceive health risks, and how they are persuaded to adopt healthy behaviors.

Theories Project.—The goal of the Theories Project is to identify and carry out activities that will help develop improved theories of health behavior. Its focus is on actions that individuals can take to prevent cancer and speed its early detection. Among the activities that may be considered are training in theory development and testing for health behavior researchers who lack such training; recruiting scientists

with strong theory orientations to cancer behavior research; development of state-of-the-art summaries of theory-relevant topics when these are lacking; and better communication of opportunities for theory-focused research among current types of NCI grants. We ask Congress to support NCI's behavioral science research and training initiatives and to encourage other institutes to use these programs as models.

I would now like to turn to some cross-cutting initiatives in which behavioral research plays a critical role.

Translational Research in Behavioral Science.—Several institutes have demonstrated enormous leadership in promoting translational research in behavioral science, aimed at bringing knowledge from the laboratory into clinical research and application. In simplest terms, this is the result Congress was looking for when it chose to double NIH budget: the results of research being used to treat patients with complex disorders in an effective and efficient manner. At NIMH, for example, they will develop research centers that support the transition of basic behavioral science research to patient-oriented studies regarding new interventions and delivery of services for patients with mental disorders. The goal is to develop more effective, theory-based interventions and service-delivery models for mental disorders through increased applications of the garnered data. At NIDA, the translational research branch (TRB) identifies basic research discoveries in the field of drug abuse research, and related disciplines, that have potential practical impact in the treatment and prevention of disease or the development of new research technologies. Once findings with practical applications are identified, the TRB actively facilitates the translation of these basic research data into clinical and research tools, medications and treatments. And at NIAAA, investigators funded by the institute have been learning a great deal about the neuroscience and biology of the problem, for example charting the brain activity of binge-drinking laboratory animals to discover what changes in neurotransmitter pathways affect the craving and reward systems that contribute to at-risk drinking behaviors.

It's not possible to highlight all of the worthy behavioral science research programs at NIH. In addition to those I've discussed here, many other institutes play a key role in NIH behavioral science research enterprise. These include the National Institute on Aging, the National Heart Lung and Blood Institute, the National Institute of Child Health and Human Development, the National Institute of Neurological Disorders and Stroke, and within NIH Director's office, the Office of Behavioral and Social Sciences Research. Behavioral science is a central part of the mission of each of these, and each deserves the Committee's support.

Obesity.—Obesity is a health problem all too often overlooked, yet recently it has begun to receive the attention it is warranted. We are glad to see Congress take up the issue in such pieces of legislation as H.R. 716, which is directed at fighting obesity and promoting improved nutrition and increased physical activity in the United States. As the legislation notes, behavior will play an important role in this effort. Motivation, counseling, marketing and communication are all important tools if we are to create a healthier nation led by healthier children. If we are to see results, the message that we communicate must be rooted in science and research. Evidence based research, translated into practice, will ensure safe and effective messages. The use of science in promoting behavioral changes should not and cannot be ignored. It has shown us that obesity leads to increased risk of diabetes, heart disease, and even cancer.

The National Heart, Lung and Blood Institute concluded that a significant proportion of coronary heart disease is caused or exacerbated by behavioral factors, including high-risk behavior. But preventing obesity could save $50 billion a year in health care costs, and recommended treatments for over-weight individuals begins with behavioral programs that include diet, exercise and training in behavioral techniques. The behavioral and physiological changes that occur during high-risk periods for weight gain must be clarified. This information can then be used to design individualized interventions, in order to prevent future weight gains and obesity. Research in this field benefits not only NHLBI, but other institutes as well, such as NICHD, NIDDK, and NCI.

This concludes my testimony. Again, thank you for the opportunity to discuss NIH appropriations for fiscal year 2004 and specifically, the importance of behavioral science research in addressing the Nation's public health concerns. I would be pleased to answer any questions or provide additional information.

PREPARED STATEMENT OF THE SOCIETY OF GENERAL INTERNAL MEDICINE

The Society of General Internal Medicine (SGIM) is pleased to present the Senate Labor, Health and Human Services and Education Subcommittee with testimony regarding fiscal year 2004 appropriations for key programs within the Department of Health and Human Services.

SGIM is an international association of 3,000 physicians and other health professionals who combine treating patients with teaching and conducting research. SGIM is dedicated to improving patient care, medical education, and research in primary care and general internal medicine. SGIM believes it is uniquely positioned to recommend appropriate funding levels to continue the important work of the Title VII and VIII Health Professions Programs and the Agency for Healthcare Research and Quality (AHRQ).

TITLE VII AND VIII HEALTH PROFESSIONS PROGRAMS

As healthcare professionals, researchers and teachers, we are concerned that sufficient, stable funding be directed towards the important work of the health professions and nursing education programs under Title VII and VIII of the Public Health Service Act. These programs help ensure that health care professionals are trained to provide quality care, represent the diverse makeup of the general population, and are available to communities across the country, particularly those in underserved areas.

SGIM recommends a 2004 budget of $550 million for the Title VII and VIII health professions programs, of which at least $40 million should be directed to general internal medicine and general pediatrics training.

By providing support to students, programs, departments, and institutions, the health professions program improves the accessibility, quality, and racial and ethnic diversity of the health care workforce. These programs help combat health professional shortages in rural and underserved areas by educating and training primary care providers who are more likely to serve in such areas. Title VII grants provide the only federal funding dedicated to the education and training of the primary care workforce. Well-trained primary care physicians are a necessity to provide care to the uninsured and underinsured, particularly in underserved areas. Data proves that one half of primary care providers trained through Title VII programs go on to work in underserved areas, compared to ten percent of those not training through a program funded by this cluster.

Within primary care, funding for general internal medicine and general pediatrics training supports medical student training, residency training, faculty development, and development of academic administrative units. Aside from increasing the number of physicians choosing general internal medicine, these programs have also proven to increase the diversity and cultural competency of the workforce. Title VII general internal medicine residency programs graduate two to five times more minority and disadvantaged students than programs that do not receive such support.

SGIM is disappointed that the Administration's budget plan for fiscal year 2004 virtually eliminates the entire Title VII program and provides no funding for the Title VII primary care cluster, which includes general internal medicine. The President's plan increases funding for community health centers and the National Health Service Corps to meet the health care needs of the uninsured and underinsured. While these programs are important, the President's budget provides little to no funding to train the health professionals who could enter the corps and serve at these health centers. SGIM commends the Senate for approving the Specter-Harkin amendment to the budget resolution, which provides further funding for the Health Resources and Services Administration (HRSA) specifically for the health professions programs. SGIM urges the subcommittee to not just restore the President's proposed cuts to these programs, but to increase their funding due to the vital need for a well-trained health professions workforce.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

SGIM strongly supports AHRQ's mission and work to support, conduct, and disseminate research that improves access to and outcomes and quality of health care services. SGIM consequently believes a fiscal year 2003 budget of at least $390 million is necessary for AHRQ to fully carry out its congressional mandate to improve health care quality, including reducing errors in medicine and advancing health outcomes information.

The agency's health services research complements the biomedical research of the NIH by helping clinicians, patients, and health care institutions make choices about what treatments work best, for whom, when, and at what costs. AHRQ is the only

federal agency that explicitly looks for ways to improve the delivery of health care services, in terms of increased effectiveness, increased quality, increased cost-effectiveness, and with fewer errors. The agency's research on error reduction addresses an important public concern, saves lives, and saves money by reducing costs of mistreatment and medical malpractice expenditures. Much of AHRQ's research addresses the cost-efficiency of new modalities or interventions and the appropriateness of their application for large patient sub-populations such as those served by Medicare and Medicaid.

AHRQ supported the development of "cardiac predictive instruments," which predict patients' probability of having an acute cardiac ischemia (a heart attack or unstable angina pectoris, that leads to heart attack) and outcomes (e.g. death or cardiac arrest). An AHRQ-supported clinical effectiveness trial of the ACI-TIPI diagnostic predictive instrument built into electrocardiographs reduced unnecessary hospitalizations the equivalent of 200,000 people per year in the United States, with an estimated savings of $728 million per year. An error reduction version of the ACI-TIPI, also built into electrocardiographs, shows promise to reduce the equivalent of $1.2 billion per year in malpractice costs for missed heart attack diagnoses. The use of an AHRQ-supported predictive instrument, the Thrombolytic Predictive Instrument, improved the use of thrombolytic ("clot-buster") therapy and angioplasty for heart attacks, especially for patients more often missed and in community and rural hospitals.

Another example is the finding by an AHRQ Evidence-based Practice Center that children suffering from uncomplicated acute otitis media (AOM), a middle ear infection, and treated with amoxicillin fared just as well as those treated with more expensive antibiotics. This research represents large cost savings to the Medicaid program since pediatricians can prescribe the less expensive medication and achieve the same result.

To the extent that it's budget allows, AHRQ collaborates with other Department of Health and Human Services (HHS) agencies, particularly the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). These collaborative efforts are critical in the translation of the fruits of the NIH biomedical research into effective clinical practice. The combination of the specific applied focus of the AHRQ with NIH research remains an opportunity for increased benefit from greater investment.

The private sector cannot replace the work of AHRQ. The private sector puts a relatively small amount of financial resources toward initiatives similar to AHRQ research, focused primarily on products developed by the specific company. Moreover, the agenda of those sectors selling health care services and goods is to increase the use of their product, not to look for the most cost-effective solution. And while health plans indeed do have motive to improve cost-effectiveness, because they are in a competitive market with enormous fiscal constraints, they do not cooperate in making cost-effective high quality care generally available to the public as AHRQ does.

The President's proposed budget for AHRQ for 2004 would be an eight percent decrease from the agency's 2003 funding level. It would allow for no new grants, and would cause current, non-patient safety grants to be cut by 15 percent. Reductions in the AHRQ funding stream will result in lost opportunities for research projects currently in the middle of a two- or three-year grant cycle. Mid-course interruptions will halt some projects just as these initiatives are about to bear fruit in the form of improved patient health outcomes and reductions in healthcare expenditures. Such reductions will also have a chilling effect on individual, investigator-initiated research, a competitive process through which applicants that receive modest levels of grant funding develop initiatives with financial implications far beyond the original investment. Congress must sustain ample funding for investigator-initiated research to encourage sufficient numbers of researchers to enter and remain in this field.

SGIM sincerely appreciates the opportunity to provide testimony to the subcommittee, and would like to thank you for the subcommittee's past support of Title VII and AHRQ.

PREPARED STATEMENT OF THE SOCIETY FOR NEUROSCIENCE

Good morning Mr. Chairman and members of the Subcommittee. I am pleased to be here today to testify before the subcommittee. I am Dr. Huda Akil and I serve as the President of the Society for Neuroscience. Our organization has a membership of over 31,000 basic and clinical researchers. We are the largest scientific orga-

nization in the world dedicated to the study of the brain, spinal cord and nervous system.

Aside from my work at the Society, I am the Gardner Quarton Distinguished University Professor of Neuroscience in Psychiatry at the University of Michigan. I am also the Co-Director of the Mental Health Research Institute in Ann Arbor. I study the biology of the emotional circuits in the brain along with the impact of the environment on these circuits. My work focuses on stress, mood disorders, and substance abuse.

Psychiatry, neurology and neurosurgery are the better-known medical specialties that have their basis in neuroscience, but this research has an impact on numerous other medical specialties. Understanding the development and function of the brain is essential to understanding the impact of a wide variety of other diseases and disorders. For example, there is ample evidence that depression increases the likelihood of heart disease and that in turn heart disease can trigger severe depression. Obesity is a major health issue in our country, and the control of feeding behavior and metabolic activity is controlled by the brain. Therefore, the science of the brain can have great impact on the overall mental and physical health of this nation.

We are pleased that Congress included funding in the fiscal year 2003 omnibus spending bill to complete the final phase of doubling for the National Institutes of Health (NIH). We recognize that the advances in basic research would not be possible without this subcommittee's strong commitment to biomedical research. Doubling the NIH budget provides an excellent foundation to continue progress in understanding and providing cures for diseases.

NEUROSCIENCE RESEARCH CENTER

The Society for Neuroscience is also pleased that the conference agreement includes language granting authority for the construction of the first and second phases of the John E. Porter Neurosciences Building. The Neuroscience Research Center will house research programs conducted by intramural neuroscience researchers from nine institutes. While all disciplines benefit from collaborative research, neuroscience, in particular, thrives on it. Different types of neuroscience research are currently conducted at various NIH institutes. Thus, the Neuroscience Research Center provides a forum for collaboration amongst leading researchers at different institutes to work together, and with the extramural research community, to further neuroscience research discoveries.

FUNDING RECOMMENDATION

We appreciate this subcommittee's commitment to significant budget increases for the NIH, especially in light of the difficult budget allocations imposed on the subcommittee.

The Society is concerned that the Administration's request for fiscal year 2004 funding for NIH may not provide adequate resources. The fiscal year 2004 budget would provide $27.9 billion for NIH, a net increase of $549 million, or 2.0 percent, over the fiscal year 2003 request. We are concerned that the progress that has been made in the years of doubling will cease its momentum. As the Chairman and members of the committee understand, scientific research builds on previous discoveries. To maintain this nation's world-renowned excellence, we must maintain the commitment exemplified in the years of doubling. This research will help us understand the biological basis of disease and, in turn, develop strategies to prevent, diagnose, treat, and finally cure such diseases.

The relatively new threat of bioterrorism has added another dimension to biomedical research. In addition to curing already existing conditions, researchers have to plan for the contingency of an induced plague or influx of disease inducing germs. This not only exhausts resources, but also affects the nation's mental well-being. Individuals who already suffer from psychiatric diseases are profoundly affected by the added stress from the threat of bioterrorism. As importantly, individuals who are healthy but are vulnerable to stress can become ill, either physically or psychologically, as a result of threats to their safety. Understanding how to cope with these psychosocial factors can be scientifically based and can become part of our national effort to combat terrorism and its long-term effects.

INCIDENCE AND ECONOMIC BURDEN OF NEUROLOGICAL AND PSYCHIATRIC DISEASES

Each year, we try to convey the importance of biomedical research in terms of longer, healthier lives for those who suffer from debilitating neurological and psychiatric disorders. It is in the economic costs and burdens that the impact of these diseases is measurable. For example:

—All Depressive Disorders affect 18.8 million Americans and cost $44 billion per year
—Hearing lost costs the United States $56 billion per year, on the 28 million Americans affected
—Alzheimer's Disease affects 4 million Americans and costs $100 billion a year
—4 million people are affected by stoke, which costs the United States $30 billion per year
—$32.5 billion per year is spent on the 3 million Americans that have schizophrenia.
—1.5 million Americans are affected by Parkinson's Disease at a cost of $15 billion per year
—Multiple Sclerosis affected 350,000 Americans at a cost of $7 billion per year

As you know, the federal government, particularly the National Institutes of Health, is the nation's leading supporter of biomedical research. We need only look at recent history to see the progress of biomedical research. Where a disease like epilepsy or cancer once meant a death sentence, today we have an arsenal of methods to manage these disorders.

Recent achievements in neuroscience made through NIH-funded research demonstrate that our nation's commitment to biomedical research has been worth the investment. I would like to discuss some of the research being done in my area of expertise.

RECENT ADVANCES IN UNDERSTANDING AND TREATING MENTAL DISORDERS

My research group works on the brain basis of mood disorders—major depression, manic-depressive illness (also called Bipolar Disorder), anxiety, panic, obsessive-compulsive illness and other mood disorders. These are brain illnesses that affect the patients' mood and shape their view of themselves and the world around them. For example, a severely depressed individual can see himself or herself as worthless, feel a sense of hopelessness and despair and suffer from intense psychological pain. This illness can be fatal as the suffering leads many to suicide and devastates entire families, wreaking havoc across generations. Even for those who survive, the illness can produce indelible changes in the brain. Repeated episodes of severe depression can lead to changes in brain structure and function that may be irreversible, and have been likened to "scarring". It is therefore critical to avoid repeated episodes to minimize either the fatal consequences or the long-term impact on brain function.

It should be noted that there is a close link between mood disorders and substance abuse. Many people use drugs because they are struggling with anxiety or other dark moods, or are unable to deal with stress. They seek alcohol and other drugs to alleviate these feelings. In turn the use of drugs, even if first triggered by other causes such as thrill seeking or peer pressure, can often lead to mood disorders. Stimulants such as cocaine, or narcotics such as heroin, alter mood. The body becomes dependent on their presence, and when they are withdrawn, severe changes in mood occur, sometimes leading to serious psychiatric consequences. Thus, understanding the brain biology of mood disorders is relevant across many arenas, including alcoholism and substance abuse.

Until recently, we thought of mood disorders as a sign of weakness, a problem that can be remedied by "toughening up" or "looking on the bright side". But neuroscience research has taught us that moods are the results of intricate activity in the brain, and therefore have a physical basis. Depressed individuals are literally trapped in a chemical imbalance that disrupts how they feel, think and judge. This insight has led brain scientists to re-frame the question of mood disorders very differently, not in terms of strength of will, but in terms of biological causes and drug treatments. Not only is this a non-judgemental and more humane approach to human suffering, but it has spurred significant scientific advances that are helping millions of people all over the world.

Neuroscientists have worked for many years to elucidate the chemical mechanisms in the brain that underlie emotions such as anxiety and whose malfunction may be at the root of depression. For example, many studies have implicated the transmitter serotonin in the chemical imbalance of depression. This view has resulted in the development of drugs like Prozac, a so-called Specific Serotonin Reuptake Inhibitor (SSRI). Prozac and other SSRI's are now widely used for the treatment of depression and help a large proportion of patients with the illness. These drugs also help with a number of other disorders including anxiety and obsessive-compulsive disorders and chronic pain.

However, some depressed individuals are "treatment resistant", in that they do not respond to SSRI's or other classes of antidepressant drugs. Our research group has discovered that this treatment resistance is typically related to a disturbed

stress system. The body has a complex set of brain molecules and blood hormones that help it cope with stress. Huge demands on this system can have severe consequences on the brain, including remodeling of the brain in an adverse manner. We have shown that those individuals that have a highly disrupted stress system often do not respond to antidepressant treatments. Therefore, there are numerous pharmaceutical company efforts aimed at discovering new classes of antidepressant drugs, many of which are aimed specifically at "resetting" the stress system. New antidepressant drugs that are in various phases of testing include blockers of the brain stress hormone CRH and of the brain receptor that recognizes the steroid stress hormones that circulate in the blood and bathe the entire body (the Glucocorticoids).

In addition, we are exploring exciting research frontiers for discovering the causes and devising new treatments for mood disorders, especially the more genetically based bipolar illness. These efforts take advantage of the results of the Human Genome Project. They aim to uncover specific genes that are active in the emotional parts of the brain and may contribute to the cause and the course of mood disorders. New technologies, including a tool known as a microarrays or "Gene Chips", are helping in this undertaking. A gene chip allows scientists to examine the activity of tens of thousands of genes at the same time and determine whether the pattern of activity in a particular brain region is altered under certain illnesses. Recent work, funded by the NIMH, as a large collaborative project between my laboratory and several other laboratories in Michigan, Stanford and the University of California, is providing exciting new insights on genes whose activity is altered in the brains of severely depressed individuals, and another set of genes altered in the brain of bipolar individuals. Thus, this research is leading us to the identification of patterns of gene activation that associate with specific mental disorders. More importantly, this research is generating a host of new ideas on how to understand the causes and improve the treatment of mental disorders.

These and many other efforts from numerous talented scientists working both with animals and with humans give us hope that we will continue to make great strides the huge proportion of Americans that suffer from a brain disorder at some point in the course of their lives.

SOMATIC CELL NUCLEAR TRANSFER

I would also like to mention an innovative therapy that offers hope to the millions of people who are affected by neurological diseases. Somatic cell nuclear transfer (SCNT), also referred to as therapeutic cloning, is one of the most promising medical research procedures on the horizon. SCNT involves removing the nucleus of an egg and replacing it with the material from the nucleus of a "somatic cell." This could be a cell from the skin, the heart, or a nerve. The egg is never fertilized by sperm. The sole purpose of this technology is to develop treatments for disease. With this research, scientists may find cures for diseases and disabilities ranging from juvenile diabetes to Alzheimer's disease.

Ethical scientists would agree that human cloning for the purpose of reproduction is reprehensible. The Society for Neuroscience supports a ban on reproductive cloning complete with criminal and civil monetary penalties. However, we strongly believe that the promise of SCNT is too compelling to be ignored. Permitting critical therapeutic cloning research will keep hope alive for millions of Americans with crippling and life-threatening diseases.

CONCLUSION

We have made great strides. Basic researchers know more today than scientists twenty years ago could even dream of understanding. Yet millions still suffer. We are committed to eradicate more diseases and ease suffering of individuals with these diseases and those who care for them. With this subcommittee's help, we hope to continue to make extraordinary inroads to understanding diseases and successfully curing them

Thank you again, Mr. Chairman, for the opportunity to testify.

PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES

On behalf of The Humane Society of the United States (HSUS) and our more than 7 million supporters nationwide, we appreciate the opportunity to provide testimony on our top funding priority for the Labor, Health and Human Services, and Education Subcommittee in fiscal year 2004.

PAIN AND DISTRESS RESEARCH

An estimated 40 percent of the National Institutes of Health (NIH) budget—or currently more than $11 billion—is devoted to some aspect of animal research. At this time, no funding is set aside specifically for research into alternatives that replace or reduce the use of vertebrate animals in research or that reduce the amount of pain and distress to which research animals are subjected. NIH may receive $27.7 billion in fiscal year 2004 if Congress fulfills the President's budget request. Out of this funding, we seek $2.5 million (.009 percent) for research and development focused on identifying and alleviating animal pain and distress. We recommend that this R&D be conducted under the National Center for Research Resources (NCRR, responsible for NIH extramural funding). We also urge the Committee to specify in report language that NCRR should conduct this research in conjunction with, or "piggy-backed" onto, ongoing research that already causes pain and distress. No pain and distress should be inflicted solely for the purpose of this research, given the volume of existing research (we estimate a minimum of 20–25 percent of all animal research) that is believed to involve moderate to significant pain and/or distress.

In 1987, NIH announced a program to award grants for "research into methods of research that do not use vertebrate animals, use fewer vertebrate animals, or produce less pain and distress in vertebrate animals used in research." Many of the 17 program awards made from 1987 to 1989, totaling approximately $2.4 million, involved research on non-mammalian models, including projects on frogs, mollusks, and insects. Other awards included mathematical modeling and computer studies. This program, which was managed out of the Division for Research Resources (the precursor to NCRR), no longer exists at NIH, and it has not been replaced by any similar program.

A 2001 survey conducted by an independent polling firm indicates that concern about animal pain and distress strongly influences public opinion about animal research in general. Public support for animal research declines dramatically when pain and distress are involved: 62 percent support animal research when pain and distress are minimal, only 34 percent when moderate, and an even smaller 21 percent when animal suffering is severe. Despite this public concern, NIH has not continued to sponsor R&D exploring how to minimize animal suffering and distress in the laboratory.

During the past five years, HSUS has been reviewing institutional policies and practices with respect to pain and distress in animal research. We have found that research institutions have inconsistent policies due to the lack of information on this subject, and that standards vary greatly from one institution to another. Painful techniques, such as the use of carbon dioxide to euthanize rats and mice, are widely practiced and approved even though studies indicate that carbon dioxide exposure for only a few seconds causes acute distress to humans. The federal standard for determining laboratory animal pain specifies that, if a procedure causes pain or distress to humans, it should be assumed to cause pain and distress to animals. While human experience can and should provide a useful guide in some cases, there are others in which humans are never subjected to the conditions facing laboratory animals. Information on pain and distress that animals themselves actually experience is important. For many accepted laboratory practices there is no scientific data regarding the painful or distressing effects on either people or animals.

A lack of data on the recognition, assessment, alleviation, and prevention of pain and distress in laboratory animals is commonly cited by scientists as a rationale for either not reporting pain and distress or not acting to mitigate it. This lack of data is obviously detrimental to the welfare of animals used in research, but it is also detrimental to the quality of science produced. Uncontrolled, undetected, and unalleviated pain, physical distress, or psychological distress result in alterations in physiologic and behavioral states, and confound the outcome of scientific research. Ultimately, the lack of information on pain and distress leads to misinterpretation of research results that could result in harmful effects in human beings when preclinical animal research results are applied to humans in clinical trials. It is worth noting that researchers themselves often comment publicly at scientific meetings about the urgent need for funding in order to properly understand and mitigate pain and distress in research animals.

Our nation takes pride in leading the world in biomedical research, yet we lag behind many other countries in our efforts to minimize pain and distress in animal subjects. For example, the United Kingdom, Sweden, Switzerland, Germany, the Netherlands and the European Union all have committed funds specifically for the "three R's" (replacing the use of animals, reducing their use, and refining research techniques to minimize animal suffering).

We urge the Committee to make this small investment of $2.5 million to promote animal welfare and enhance the integrity of scientific research. We also respectfully request this accompanying committee report language:

"The Committee provides $2.5 million for the National Center for Research Resources to support research and development focused on improving methods for recognizing, assessing, and alleviating pain and distress in research animals. No pain and distress should be inflicted solely for the purpose of this initiative, since the investigations can and should be conducted in conjunction with ongoing research that is believed to involve pain and distress under Government Principle IV of Public Health Service Policy, which assumes that procedures that cause pain and distress in humans may cause pain and distress in animals."

Again, we appreciate the opportunity to share our views and top priority for the Labor, Health and Human Services, and Education Appropriation Act of fiscal year 2004. We hope the Committee will be able to accommodate this modest request that will benefit animals in research and the quality of the research. Thank you for your consideration.

PREPARED STATEMENT OF THE NATIONAL MULTIPLE SCLEROSIS SOCIETY

Mr. Chairman and distinguished members of the Subcommittee, we appreciate the opportunity to submit written testimony on behalf of the National Multiple Sclerosis Society. The Society is the world's largest private voluntary health organization devoted to the concerns of all those affected by MS. Throughout our 57-year history, we have maintained a commitment to research to help us better understand MS and to apply this knowledge to the development of new treatments and ultimately a cure. The Society awarded its first three research grants in 1947, and our commitment to research has steadily grown. This year we will invest $30.1 million in research.

Multiple sclerosis is a chronic, unpredictable and often disabling disease of the central nervous system. Symptoms range from numbness in the limbs, to loss of vision, and in some instances partial or total paralysis. The progress, severity and specific symptoms of MS in any one person can vary and cannot yet be predicted, but advances in research and treatment are giving hope to those affected by the disease.

To this end, basic and clinical research conducted at NIH and research supported by NIH throughout the country is of critical importance to all people with chronic illnesses and disabilities—such as MS. Since MS is considered both a neurological and autoimmune disease, two NIH institutes are of particular relevance to our patients: The National Institute of Neurological Disorders and Stroke (NINDS)—which funds 75 percent of the MS-specific research at NIH—and the National Institute of Allergy and Infectious Diseases (NIAID)—which funds about 25 percent.

In this year's testimony, we wish to bring the following issues to the Subcommittee's attention:

—The Society's gratitude for the large fiscal year 2003 NIH increase and hope for continued balanced, increased funding for biomedical research at all NIH institutes in fiscal year 2004 and beyond.

—The cooperation and responsiveness of NINDS to the Society's inquiries concerning the coding system that tracks grant expenditures.

—Increased collaborative research efforts between NIH and the Society.

NIH FUNDING

On behalf of people with MS, the Society wishes to express gratitude for the Subcommittee's commitment to doubling the NIH budget from $13 billion in fiscal year 1999 to $27 billion in fiscal year 2003. However, to maintain this current research momentum, the Society firmly believes NIH needs an 8–10 percent increase in fiscal year 2004 funding. This increase is required to sustain critical biomedical research at NIH and to keep pace with inflation. With regard to bioterrorism research, the Society urges the Subcommittee to weigh carefully the funding allocation at NIH institutes to assure that our national security needs are met, but to still allow biomedical disease research at all institutes to grow in fiscal year 2004 and beyond.

The President's fiscal year 2004 budget request, under which NIH would receive about a 2 percent increase, is of great concern to the Society. NIH-funded research has led to advances in critical areas of discovery, such as human genetics, diagnostic testing and more targeted and effective treatments. If NIH receives a small fiscal year 2004 increase, significant pending and future scientific gains will be limited and perhaps altogether missed—potentially undermining the intent of doubling the

NIH budget. Furthermore, a 2 percent increase essentially would constitute a reduction in funding as it would render NIH unable to keep pace with inflation.

The Society recognizes that new discoveries and breakthroughs could come from any area of biomedical research and could apply to the primary concern of our members: ending the devastating effects of MS. Knowing that a well-funded federal research enterprise is of great public benefit, we encourage Congress to focus on NIH as a whole, with balanced consideration given to the two institutes of direct relevance to people with MS—NINDS and NIAID.

GRANT RECODING PROCESS AT NINDS

In 2000, NINDS changed its procedures for coding and tracking of grants and consequently, the Society was surprised that reported fiscal year 2000 expenditures on MS research dropped about 46 percent (to $40.3 million). The Society is pleased to report to the Subcommittee that in 2002, the Society worked closely with NINDS leadership to understand, correct and improve the institute's coding system. As a result of this effort and after close review, we have determined that the NINDS actual fiscal year 2002 support of MS-related research was $65.6 million, a figure that now better represents the institute's investment in MS. We will continue our efforts to ensure optimal procedures are used to track the federal investment in MS-related research at NINDS, NIAID, and NIH-wide.

COLLABORATION WITH NIH

Last year, we raised concerns to the Subcommittee about our experience with the lead NIH institute in MS research with regard to joint collaborative research projects in MS. We are pleased this year to report increased interest in collaborative research and other activities by NINDS and NIAID.

NINDS

The Society currently is working closely with NINDS on a joint workshop to foster the development of a collaborative and international MS genetics network. Titled "Genetics and Multiple Sclerosis: Future Prospects," this workshop will bring together leaders in the field of MS genetics along with the Society's senior scientific advisors. This workshop will provide an opportunity to review the state of the art in the field and to discuss strategies for small and large-scale studies utilizing the latest technology and cost-effective approaches to finding the genes that confer susceptibility to MS.

NIAID

In 2001, the Society entered into a collaborative agreement with NIAID to research "Sex-based Differences in the Immune Response." Such collaboration extends the reach of the Society's own targeted research initiative on gender differences in MS by encouraging basic and clinical investigation of disparities in immune responses between men and women and provides wider visibility of the problem and opportunities. Initiated as an effort of the NIAID, other NIH institutes, including NINDS, came on board to provide co-funding for a one-time request for applications. Together, our agencies co-funded six research projects relevant to MS, as well as projects related to other autoimmune diseases and to the immune function in general.

Collaborative activity leverages the resources of all parties engaged in the effort. In the current environment of fiscal constraints and numerous national spending priorities, collaborative research across public and private sectors and scientific disciplines presents a significant opportunity to leverage the research investment of all involved parties. We ask the Subcommittee to encourage continued collaboration among NIH institutes as well as outside the boundaries of the federal government, and we look forward to continuing our collaborative efforts with NIH institutes.

We thank the Subcommittee for this opportunity to comment and applaud your steadfast commitment to advancing the health and well-being of all Americans through substantial investment in biomedical research.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

The American Association of Immunologists (AAI), a non-profit professional association of more than 6,500 research scientists and physicians dedicated to understanding the immune system—resulting in the prevention, treatment, and cure of disease—appreciates this opportunity to express its views on the fiscal year 2004 Budget for the National Institutes of Health (NIH). Before we do, we would like to

express our deep appreciation to the members of this subcommittee and to its chairman and ranking member, Senators Arlen Specter and Tom Harkin, for your extraordinary support for biomedical research and the NIH. AAI was very proud to present Senators Specter and Harkin with our 2001 Public Service Award, "in recognition of their outstanding leadership, achievements, and advocacy on behalf of biomedical research and the National Institutes of Health." We are grateful for your continuing leadership and unwavering dedication to government sponsored biomedical research and the scientists this funding supports.

IMMUNOLOGY

The study of immunology spans a wide range of diseases and conditions which affect the lives of every American. Our scientists use grants from the NIH, and in particular from the National Institute of Allergy and Infectious Diseases (NIAID),[1] to understand the workings of the immune system. This information allows for delineating the causes of disease and discovering treatments and potential cures. Immunologists are currently engaged in many such activities, including:

—developing effective vaccines against HIV/AIDS, influenza, and other infectious and chronic diseases;
—discovering new defenses against emerging and re-emerging bacteria (such as tuberculosis) and drug resistant bacteria (including antibiotic-resistance);
—regulating autoimmune diseases such as diabetes, myasthenia gravis, rheumatoid arthritis, and lupus;
—discovering the causes of cancer and promising new treatments; and
—developing treatments to prevent the rejection of transplanted organs and bone marrow.

With all of this research ongoing, immunologists have also recently begun important work on urgently needed biodefense research, much of which was funded in the fiscal year 2003 appropriations bill. Because AAI members include the nation's preeminent immunologists, many of our members are already conducting research that is at the forefront of the nation's urgently needed vaccine development and related biodefense research efforts. The work of immunologists will be critical in understanding both the mechanism of infectious diseases and recovery from them.

As we discuss this year's budget, we would also like to discuss the unique role that we believe immunologists are playing in the national effort to combat bioterrorism.

THE NIH BUDGET IN THE POST "DOUBLING" ERA

AAI is immensely grateful to Chairman Specter and Senator Harkin, and to the members of this subcommittee, for initiating and shepherding the successful effort to double the budget of the NIH over five years, an effort which was completed during the fiscal year 2003 appropriations process. We cannot emphasize enough the importance of this extraordinary commitment to the research enterprise, both in terms of securing additional research dollars and for the "shot in the arm" to biomedical researchers all over this nation. Just as our troops overseas depend on both financial and emotional support from home to succeed in their mission, so do those on the "home front" who are fighting a war against illness and disease—whether caused by natural agents or by man-made agents of bioterror. The recent boost in NIH funding has put NIH and the scientists it funds on a trajectory for rapid progress and ultimate success.

GENERAL BIOMEDICAL RESEARCH

AAI strongly believes that future NIH budgets must continue to recognize the critical importance of biomedical research funding both as a tool to prevent and treat disease and as an urgent defense against the threat of bioterrorism. We believe that—to capitalize on the momentum that has resulted from doubling of the NIH budget—NIH must now receive increases that are sufficient to support this large bipartisan investment in biomedical research. In this regard, AAI recommends a 10 percent increase in funding for NIH for fiscal year 2004. Such an increase—if properly allocated—will allow more quality research to be funded, leading to more translational opportunities and swifter clinical application; help attract young Americans to research careers; and help retain young, promising scientists (who might

[1] Many AAI members also receive grants from the National Cancer Institute (NCI), the National Institute on Aging (NIA), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of General Medical Sciences (NIGMS), and other NIH Institutes and Centers.

otherwise leave academia or government for better rewarded opportunities with pharmaceutical or biotech companies).

As you know, the President's fiscal year 2004 budget proposes a budget of $27.893 billion, a 2 percent increase over the fiscal year 2003 budget. According to the Administration, the actual increase in funding for "research programs and support" will be 7.5 percent "as a result of converting approximately $1.4 billion from one-time non-recurring costs in fiscal year 2003 for facilities construction and anthrax vaccine procurement. . . . [*Department of Health and Human Services Fiscal Year 2004 Budget Summary* ("HHS Budget Summary"), page 31] Administration officials concede, however, that with biodefense research growing at a faster rate, non-biodefense research will increase only 4.3 percent.[2] [National Institutes of Health, Summary of the President's Budget, February 3, 2003 ("NIH Budget summary"), p.1] AAI is very concerned that this increase is too small to both support ongoing research and permit funding of a sufficient number of new and competing continuation grants. In addition, this increase will not support the continued enhancement of pre- and post-doctoral stipends (see p. 5).

BIODEFENSE RESEARCH

The Administration proposes a slight decrease in NIH biodefense funds, requesting $1.6 billion in fiscal year 2004. Once again, Administration officials consider this $121 million reduction a result of "significant one-time, non-recurring biodefense expenses in fiscal year 2003 . . .," resulting in an increase of $875 million in fiscal year 2004. (HHS Budget summary, p. 32) AAI supports this level of biodefense funding, and in particular (as described below), strongly supports the request for 125 FTEs for biodefense research activities.

While the infrastructure funding provided in the 2003 appropriation was both needed and welcome, it does not provide all of the needed facilities for biodefense research (see p.3), nor does it provide funding for the additional security costs mandated by the Patriot Act both as one time costs and for ongoing security required at facilities which conduct research on select agents. In addition, this important research cannot get done without adequate NIH intramural staff to award the grant funding and to provide necessary administrative and oversight functions. It is vitally important, therefore, that the NIH professional staff be increased to oversee the biodefense research and that they be provided with sufficient administrative and fiscal support personnel. We urge the Congress to provide NIH with these and any other resources it needs to ensure the expedited distribution, efficient use, and sound stewardship of federal biodefense funds.

Project BioShield.—While we have not yet had an opportunity to review the details of the proposed Project BioShield, we look forward to working with the Administration and the Congress on this program.

Construction of New High Containment (BSL3/BSL4) Laboratories.—Work on many select agents as well as other pathogenic bacteria, viruses, and fungi require biological and physical containment. One of the limiting factors in the ability of the research community to perform critical work relating to the cause, treatment, and cure of these disease-causing organisms is the relative scarcity of physical laboratories that are equipped to allow a safe working environment for both the investigator and the community.

BSL4 laboratories provide the highest level of containment. While there is currently a shortage of BSL4 labs, several new facilities are coming on line and will certainly ease the cues of experiments to be performed in the existing BSL4 facilities. There does, however, remain a need for additional BSL3 facilities that are adequately secured for use with select agents. These labs, while used for less dangerous select agents, have many advantages: they can be used for experiments on many biohazardous agents; they can be accommodated in many different physical buildings; and their operational costs are much lower than for BSL4 facilities. AAI supports the construction of additional BSL3 facilities at institutions around the country to allow access of investigators who have important projects requiring this standard of protection.

Just as important as the construction of new high containment laboratories is ensuring adequate training in their use. AAI urges the Congress to support programs which enable graduate students, post-doctoral fellows, and senior investigators to obtain proficiency training to allow them to work in biohazard labs. Such programs could be in the form of brief training periods or as supplements to existing training grants.

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[2] The President's fiscal year 2004 proposed budget indicates that the average cost of research project grants will increase in the aggregate by only 2.7 percent. (NIH Budget summary, p. 5)

THE ROLE OF IMMUNOLOGISTS IN THE NATIONAL RESPONSE TO BIOTERRORISM

Because immunologists study the immune system in health and disease, we have both a special interest and expertise in the nature of infections. We have a unique ability to study the normal immune response to the bacteria and viruses which could be used as weapons of bioterrorism. An important aspect of the normal immune response is defining the "targets" (i.e., antigens or epitopes) the immune system uses to recognize and destroy invading pathogens. In immunologic terms, this means defining the chemical nature of the epitopes recognized by the major defenders of the immune system—T and B lymphocytes. The mechanisms of defining epitopes are well known, but have not been applied to some pathogens which could be used as weapons of bioterrorism; these will need to be defined in the test tube, in animal models,[3] and finally, in humans. Once we understand the human immune response, we will be prepared to develop life-saving therapies and preventive vaccines. Collaboration between microbiologists, who understand the biology of infectious agents, and immunologists, who understand how the immune system recognizes and fights infectious agents, is critical.

Some exciting work in the area of biodefense is already underway. Immunologists, working in conjunction with infectious disease specialists, are using cutting edge technology to "immunize" people against agents of bioterror. Rather than using the traditional "active vaccination" approach, which requires injection of attenuated microbes or inactivated toxic molecules and a period of some weeks to months before the individual is protected from the disease and/or infectious agent, immunologists are working to develop passive antibody therapies (i.e., developing human monoclonal antibodies that can be used in vivo to neutralize and remove bioterrorist microbes and their toxic products) for prevention and treatment of infections or the toxic effects caused by selected bioterrorism agents. In many instances, this approach would be far preferable to active vaccination as it has few, if any, of the potential side effects that can occur as a result of active vaccination and provides immediate protection that will last for months. Such a therapy could be used to protect first responders and others prone to exposure in the event of a bioterrorism incident. This developing therapy has the potential to be used as protection against anthrax, plague, botulinum toxins, and smallpox, among others.

Another example of important biodefense work is research being conducted on vaccinia virus, which is used as the vaccine for smallpox. Immunologists have demonstrated through mouse models that the immune response to vaccinia virus is greatly altered when the host has previously had infections with other, completely unrelated viruses. As a result, immunologists are now studying whether adult humans who receive the smallpox vaccine for the first time may respond in different ways than children, as the adults have had a history of more infections by other viruses that could account for differences in the side effects of adult vaccination that are now being seen.

RESEARCH, MANAGEMENT AND SERVICES (RM&S) BUDGET

AAI is very concerned about the Administration's plans for the Research, Management and Services (RM&S) budget, and in particular, for the "outsourcing" portion of that plan. The significant new funding appropriated to NIH requires additional administrative staff to ensure that the money is well and properly spent. While the RM&S budget supports the management, monitoring, and oversight of intra- and extra-mural research activities (including ensuring the continuation of NIH's excellent and highly regarded peer review process), it has not kept pace with the increasing size and complexity of the NIH budget.

While the President's fiscal year 2003 budget included an overall increase of 17 percent (with an average 9 percent increase for most Institutes and Centers and a larger increase for NIAID and NCI), the President's fiscal year 2004 budget recommends an increase of only 5.3 percent. (NIH Budget summary, p. 9) As a result, only 3 percent of the NIH budget will be devoted to RM&S, continuing a decline in funding (from the 4.8 percent that RM&S received in fiscal year 1993) which has

[3] Immunologists depend heavily on the use of animal models in their research. Without the use of animals, theories about immune system function and treatments that might cure or prevent disease would have to be tested first on human subjects, something our society—and our scientists—would never countenance. Despite the clear necessity for animal research, people and organizations that oppose such research are threatening scientists who use animal models. The legal and illegal methods used by these groups to further an animal-rights/anti-medical research agenda are diverting precious resources from our work, threatening the personal safety and security of scientists, and delaying the progress of important research that is underway.

occurred even as the NIH budget—and programs supported by that budget—increase.

AAI is also very concerned about the Administration's proposal for "outsourcing." While certain jobs within NIH may be appropriate for such an approach, it should not be applied to program administration staff, many of whom are highly experienced and have historical knowledge and understanding of the programs and policies of NIH. Outsourcing such positions will undoubtedly result in the loss of a dedicated and capable workforce, reducing efficiency in the long run.

AAI believes that proper stewardship is the best guarantee the taxpayer and the Congress have that appropriated funds will support the highest quality research and lead to the most promising results. We urge Congress to increase the RM&S budget, restrict outsourcing to non-programmatic activities, and permit streamlined hiring procedures to assist in the expeditious awarding of grant funds.

SALARY CAP

The President's fiscal year 2004 budget request includes a provision which was rejected by the Congress for the last two years to lower the existing salary cap for extramural researchers. As we understand this year's provision, it again proposes to "roll back" current law and result in a 10 percent reduction in salary support for some extramural researchers. This would cause serious administrative and budgetary problems within research institutions, medical schools, and universities that are preparing or have already prepared budgets based on the higher salary cap previously permitted by the Congress. We urge this subcommittee and the Congress to reject this provision and to retain current law.

ATTRACTING BRIGHT STUDENTS TO BIOMEDICAL RESEARCH AND RETAINING YOUNG RESEARCHERS

AAI has long been concerned about science's ability to attract bright young students to careers in biomedical research to ensure the future supply of biomedical researchers. In particular, we have worked to advance the plight of post-doctoral fellows who are significantly underpaid and under-compensated for their critical work. We were very pleased, therefore, when the NIH announced in March of 2001 that it intended to implement recommendations of the National Academy of Sciences' Committee on Science, Engineering, and Public Policy (COSEPUP) regarding the need for better compensation and employment benefits for post-doctoral fellows. (See NIH NOT–OD–01–027). The final NIH plan included increasing the stipends for the Ruth L. Kirschstein National Research Service Awards (NRSA) recipients over a five year period by 10 percent per year or until entry level post-doctoral fellows reach $45,000 per year (from its fiscal year 2002 level of $31,092). During fiscal year 2002 and fiscal year 2003, the NIH did raise stipends by 10 percent. The President's fiscal year 2004 budget, however, permits only a 4 percent increase for pre-doctoral fellows (from the current stipend level of $19,968), and from 4 percent to 1 percent, based on years of experience, for post-doctoral fellows. We do not believe that this increase, which would result in an annual stipend of $35,560 for first year post-doctoral fellows (and includes few, if any, fringe benefits), provides adequate support for post-doctoral scientists, many of whom are in their thirties, are married, have children, and are trying to buy homes, save for their children's college educations, and save for their own retirement.

We strongly urge this subcommittee to enable NIH to proceed with its plan to increase NRSA post-doctoral stipends and to further explore ways to provide important employment benefits—including health insurance, pensions and Social Security, and vacation and sick leave time—to both NRSAs and the post-doctoral fellows supported by NIH extramural grants. While we understand that this may result in the hiring of fewer post-doctoral fellows, we believe that it is essential to provide a living wage and basic employment benefits if we are to attract and retain the best and brightest students who often encounter multiple job opportunities with significantly more attractive compensation packages. NIH and the National Science Foundation have both recognized this reality facing the nation's scientific community and have attempted to address this problem directly—we urge the Congress to enable NIH to move forward with its post-doctoral stipend plan.

SCIENTIFIC ADVISORY COMMITTEES

AAI has been concerned about reports we have read in Science and Nature magazines as well as anecdotal evidence suggesting that various federal scientific advisory panels have been dismantled or reorganized in an effort to ensure political compatibility with specific positions of this Administration. AAI believes strongly that it is in the best interests of the public, the government which serves them, and the

advancement of science that members of government scientific advisory panels be selected on the basis of the excellence of their science, and not on the basis of their political affiliations, voting history, or religious views. In short, millions of lives—as well as the prudent use of taxpayer dollars—depend on government officials receiving—and taking—the very best and most independent scientific advice that is available. We hope that the members of this subcommittee might address this concern in report language to reassure the scientific community that the Federal Government values receiving independent scientific advice, not based on conformity with specific litmus tests.

CONCLUSION

At this writing, the Senate is just beginning consideration of fiscal year 2004 appropriations for NIH. We look forward to the hearing process, to learning more about the plans the Administration and the Congress have for advancing biomedical research at and through the NIH, and to commenting on those plans as they unfold. We will continue to embrace the many familiar research areas that are open to our scientists and to working with NIH to help educate bench scientists about the newer urgent scientific needs—and the ever-increasing scientific opportunities—that lie before us. We hope that the members and staff of this subcommittee—and the Senate—will look to us as a resource on any matters involving the immune system, vaccine development, or biomedical research in general. We appreciate having this opportunity to express our views.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF CARDIOLOGY

INTRODUCTION

The American College of Cardiology (ACC) is a 29,000-member, professional medical society and educational institution whose mission is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, and leadership in the development of standards and guidelines and the formulation of health policy. The ACC submits for the record this statement in support of fiscal year 2004 funding for the National Heart, Lung, and Blood Institute (NHLBI).

Due largely to the medical research and education programs supported by the NHLBI, many Americans who suffer from or are at risk for cardiovascular disease now have access to a greater variety of diagnostic tests, medical treatments, and information about prevention. Even with these advances, cardiovascular disease continues to claim almost as many lives each year as the next five leading causes of death combined. With the aging of the so-called baby boom generation, the number of people at risk for cardiovascular disease is only likely to grow, making it critical that recent and future discoveries be translated into practice as quickly as possible. The ACC urges the subcommittee to continue its long-standing support for the NHLBI and, specifically, for its heart-related research.

The advances in the treatment of cardiovascular disease achieved over the last several decades have saved millions of lives and improved the quality of life for many who otherwise would not have had access to the life-saving treatments they desperately needed. But because cardiovascular disease continues to afflict millions of Americans, and because researchers are on the brink of exciting new discoveries that will help prevent and treat cardiovascular disease, it is critical that the NHLBI be funded at the highest possible level.

In addition, the work of the Agency for Health Care Research and Quality has emerged as a critical partner of the research community in working to ensure the effective migration of relevant clinical research results into practice. AHRQ sponsors and conducts research designed to provide evidence-based information on health care outcomes—that is, quality, cost, use and access. The information has the potential to help health care decisionmakers—patients and clinicians, health system leaders, purchasers, and policymakers—make more informed decisions and ultimately to improve the overall quality of health care services.

THE COST OF CARDIOVASCULAR DISEASE

The total cost of cardiovascular disease in the United States in 2003 is estimated to be $351.8 billion. This figure includes direct costs, such as the cost of physicians, hospitals, nursing home services, medications, and home health care. Of the $351.8 billion, $142.5 billion is attributed to the indirect costs of lost productivity resulting from morbidity and mortality.

Cardiovascular disease claimed 945,836 lives in the United States in 2000—that is 39.4 percent of all deaths, or one of every 2.5 deaths. More than 2,600 Americans die of cardiovascular disease every day, an average of one death every 33 seconds. In addition, 150,000 Americans under the age of 65 are killed by cardiovascular disease each year. Contributing to these staggering numbers is the fact that, people who have had a heart attack run a risk of sudden death that is four to six times greater than that of the general population.

For the past five years, Congress has demonstrated its deep commitment to medical research by completing a five-year plan of doubling funding for the National Institutes of Health (NIH) by 2003. The ACC commends this dedication to medical research funding, especially in light of the constraints placed on the federal budget and competing funding priorities. The ACC believes that the completion of the doubling of the NIH budget has been an excellent down payment on a strong medical research infrastructure. Despite all that has been accomplished, the federal government should not rest on it laurels. Now is the time for Congress to demonstrate that medical research truly is a priority by continuing to increase federal support of the NIH.

TRANSLATING RESEARCH FROM "BENCH TO BEDSIDE"

The ACC believes that the expansion of large-scale clinical trials is critical if we are to translate ground-breaking research into useful practice. Clinical trials can also be an important tool for identifying early therapeutic strategies and pharmacological agents that have the potential to reduce health care costs. Many of these trials require thousands of patients to be studied over several years. In addition to expanding the number and scope of clinical trials, additional resources must be dedicated to train the next generation of clinical "trialists" in the areas of biostatistics, trial design, outcomes research, and bioethics.

High blood pressure, also known as hypertension, is a major contributor to and indication of cardiac diseases. According to recent estimates, one in four U.S. adults has high blood pressure, but because there are no symptoms, nearly one-third of these people don't even know they have it. Compared to the general population, patients with hypertension are three times more likely to develop coronary heart disease and six times more likely to develop congestive heart failure. A very recent clinical trial has shown that relatively inexpensive traditional diuretics are just as effective as newer medicines like calcium channel blockers and ACE inhibitors when attempting to prevent heart attack, stroke, and heart failure.

A recently concluded clinical trial demonstrated that patients who have normal levels of harmful low-density lipoprotein (LDL) cholesterol, known as "bad" cholesterol, can see significant benefit from drug treatments that raise the levels of high-density lipoprotein (HDL) cholesterol, or "good" cholesterol. The HDL Atherosclerosis Treatment Study (HATS) was designed to study the effect of lowering LDL and raising HDL levels on the progression of atherosclerosis in coronary disease patients. HATS found that patients who were administered a combination of the drugs simvastin and niacin not only had a significant reduction in the progression of atherosclerosis, but they also experienced a significant reduction in incidences of heart attacks, strokes, and deaths. This was important work because while the health benefits of lowering LDL levels are understood and applied in the medical community, the beneficial effects of raising HDL levels and improving the balance between LDL and HDL was not previously well understood.

The NHLBI is also currently funding a clinical trial designed to test public access to automated external defibrillators (AEDs)—devices that automatically analyze heart rhythms and deliver an electric current to the heart of a cardiac arrest victim. Researchers already know that AEDs save lives. The Public Access to Defibrillation (PAD) program is designed to measure the life-saving potential and cost effectiveness of putting AEDs in the hands of trained lay individuals. For every minute that the heart is not shocked back into rhythm, the cardiac arrest victim's chances of survival decrease by 10 percent. About one-fourth of the 300,000 annual deaths from sudden cardiac arrest occur outside the home in public areas, making it critical that more people are trained so the time between cardiac arrest and defibrillation is shortened.

Knowing the critical importance of early defibrillation, the ACC asks the subcommittee to reaffirm its support for public access to emergency defibrillation by funding community AED programs at $42.5 million for fiscal year 2004. Continued funding will be used to help communities buy AEDs and train first responders and the public in their use.

Almost 62 million Americans suffer from one or more types of cardiovascular disease. Contrary to society's belief that men are more likely to suffer from cardio-

vascular disease than women, 32.1 million women, compared to 29.7 million men currently suffer from one or more forms of cardiovascular disease. Women also typically develop cardiovascular disease later in life than men.

As women age, one of the most important health decisions they face is whether to use post menopausal hormone therapy. Until recently, studies have yielded conflicting results about the hormone therapy's effects on breast cancer, heart disease, and other conditions. Research being conducted through the Women's Health Initiative (WHI), provides new important information that women and their physicians should consider when making that choice. The NIH established the WHI in 1991 in an effort to address the most common causes of death, disability and impaired quality of life in postmenopausal women. This 15-year, multi-million dollar endeavor is important to research being done on cardiovascular disease and women and is one of the largest prevention studies of its kind in the United States. In summer 2002, WIS halted its hormone therapy study after it was found that the risks of long-term estrogen plus progestin therapy outweighed its protective benefits. The researchers found increased risks of heart attack, stroke, invasive breast cancer, and blood clots. And although the increased risks are small, when applied to the entire population of women on hormone therapy and over several years, the potential public health impact could be considerable.

If clinical research is to benefit patients, resources must be available to facilitate the transmission of clinical trial data to the general medical community. The ACC asks the subcommittee to designate funds for clinical research training and for the translation of research into practice, through the NIH and other federal agencies.

FUTURE RESEARCH AND DEVELOPMENT INITIATIVES

With adequate funding, the possibilities of medical research are endless. Each advance in cardiovascular research opens the door to other new and exciting initiatives. Increased funding for medical research through the NHLBI is needed not only so current research initiatives can continue, but so that the NHLBI can pursue new research opportunities. The ACC encourages Congress to provide funding for these and other research initiatives which NHLBI hopes to pursue in fiscal year 2004:

DNA Research

Because of the size and complexity of the human DNA puzzle, currently there are very few laboratories which are sufficiently staffed and equipped to tackle the work of narrowing long sequences of genetic code down to useable information. Genetic predisposition to certain diseases can be placed within a certain region of DNA, but narrowing the focus down to be able to pinpoint the causative gene requires highly specialized equipment and personnel. The NHLBI plans to fund a handful of laboratories to pursue the work of accurately identifying the specific genes that predispose an individual towards the development of cardiovascular disease. Research of this type has already proven effective. Last year researchers were able to identify first in mice and later in humans the gene which associated with the levels of triglyceride (a type of fat) in a person's blood. This is important because triglyceride levels are associated with a risk of coronary heart disease.

Overweight and Obesity Prevention and Control at the Worksite

Nearly two-thirds of the adult U.S. population is overweight or obese. As a result, more Americans are at risk of developing various cardiovascular problems ranging from atherosclerosis to total heart failure. Among its research opportunities for fiscal year 2004, the NHLBI plans to develop a new program that will support the design and testing of innovative worksite interventions for preventing and controlling overweight and obesity in adults. Because of the risks associated with unhealthy body weight, it is important that the current approach of appealing to individuals to control their weight is expended to include the workplace, which is a promising location to encourage healthy lifestyle changes.

Recovery of Heart Function with Circulatory Assist

The only proven treatment for end-stage heart failure is heart transplantation, but the waiting list for transplants is long. While waiting for an appropriate donor heart to be found, a mechanical circulatory assist device is utilized to stabilize a patient. There is some some evidence that the "rest" that mechanical assistant provides to the heart may actually enable the heart to recover function. The NHLBI hopes to initiate a study that will capitalize on this observation and determine the potential for sustained myocardial recovery through the use of external circulatory assistance devices, identify the kinds of patients most likely to reap reparative benefits from temporary assistance, and investigate collaborative treatment protocols which will promote cardiac tissue repair.

Mechanisms of HIV-Related Cardiopulmonary and Hemostatic Complications

"Drug cocktails" and anti-viral therapies have begun to transform the lives of individuals infected with HIV. HIV-positive individuals who receive modern treatment have seen greatly lengthened life expectancies. While these new treatments are exciting, HIV patients are now beginning to present secondary effects of infection, including serious cardiopulmonary and hemostatic complications. The NHLBI will initiate a research initiative aimed at furthering understanding the relationship between HIV infection and other diseases such as opportunistic infection of the heart, emphysema, and coagulation disorders. It is important that health care providers are given the tools to deal with both the primary effects of HIV infection and also the secondary complications which are becoming more prevalent.

Cultural Competence Academic Award

Cultural, linguistic, and social differences in populations can present barriers to effective diagnosis and treatment of cardiovascular disease. To promote the design of materials specific for cultural or ethnic groups and their dissemination throughout the medical community, the Cultural Competence Academic Award will be established as a medical-training curriculum development initiative.

THE VALUE OF PREVENTION AND EDUCATION

While the ACC stresses the continued need for increased funding for NHLBI research, new treatments and therapies are not enough to win the fight against cardiovascular disease. If we are to turn the corner in our battle, efforts must be strengthened to reduce the incidence of heart attacks, coronary heart disease, heart failure, and high blood pressure through increased patient and physician education. We know hypertension, high cholesterol, obesity, diabetes, smoking, and physical inactivity are definitively associated with heart disease. Current education programs funded by the NHLBI include the National Cholesterol Education Program, the National High Blood Pressure Education Program, the Obesity Education Initiative, the National Heart Attack Alert Program, and the Women's Heart Health Initiative. These programs are designed to make information readily available to physicians, patients, and their families.

Lipid Reduction

The leading indicator of heart disease is high cholesterol. Although many people know that high cholesterol is bad, they tend to be unaware of which levels of cholesterol are considered high or dangerous. In 2001, the NHLBI released new guidelines redefining healthy and unhealthy cholesterol levels. As a result of these new guidelines, the "Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults" (also know as the Adult Treatment Panel III [ATP III]) released in spring 2001 calls for more aggressive cholesterol-lowering treatment and for better identification of those at high risk of contracting heart disease. To inform people about these new guidelines, the NIH developed several resources to get the information out to physicians, including an "ATP III at-a-Glance" desk reverence and a Palm-OSR interactive tool. And as a way of encouraging patients to be more active partners in their care, the NIH released a new patient booklet titled, "High Blood Cholesterol—What You Need to Know," a simplified 10-year heart disease risk calculator for the public, and an updated Web site, "Live Healthier, Live Longer," that includes all the information in the ATP III study. Statins, drugs that play a key role in lowering cholesterol, while gaining popularity, are still underused. It is especially important, now that the NHLBI has lowered the levels at which cholesterol is considered high or dangerous, that people know their cholesterol levels and their options for treatment.

Obesity Prevention

One of the greatest health threats in this country and in the battle against heart disease is obesity. Over the past 20 years, obesity rates among adults and children have skyrocketed. Last year, the U.S. Surgeon General issued a "call to action" to prevent and decrease overweight and obesity. We must heed this call, otherwise we risk turning back the clock on the gains made in areas such as heart disease, several forms of cancer, and other chronic health problems. At the core of the obesity problem is poor diet and physical inactivity, which are cross-cutting risk factors that contribute significantly to deaths from heart disease, stroke, and diabetes. This country must dedicate the resources necessary to encourage more Americans to have a healthier diet and to be physically active. The ACC encourages the subcommittee to support a funding level of $65 million in fiscal year 2004 for the Division of Nutrition and Physical Activity, and $125 million to restore the Youth Media Campaign at the Centers for Disease Control and Prevention.

Promoting Heart-Healthy Lifestyles

In another effort to promote heart-healthy lifestyles in communities around the country whose residents have higher than normal mortality rates from coronary heart disease and stroke, the NHLBI has created and funded twelve Enhanced Dissemination and Utilization Centers (EDUCs), doubling the number of EDUCs in existence. The EDUCs are expected to form the foundation of a nationwide network to reduce the burden of cardiovascular disease by changing the behaviors of health care providers, patients, and the general public. The EDUCs are just one element of a larger heart-health agenda that the NHLBI launched as part of its efforts to meet the federal government's Healthy People 2010 report goals. Healthy People 2010 are the federal government's plan for building a healthier nation over the next 10 years. Its two major goals are to end racial and ethnic disparities in the burden of disease and to increase the years and quality of life for every American.

AHRQ—Moving Research into Practice

The research and education developments the federal government has facilitated are remarkable and exciting. However, the best research is of no value if it never reaches the patient. The Agency for Healthcare Research and Quality (AHRQ) is charged with ensuring that advances in medicine become the baseline for medical care. By fulfilling the mission of placing today's breakthroughs in the hands of physicians tomorrow, AHRQ injects up-to-the-minute research into day-to-day medical decisions and treatments. AHRQ has become an increasingly important partner to both the clinical research community and to the ACC and other private sector organizations as we work to develop continuous quality improvement initiatives. In addition to funding cardiovascular outcomes effectiveness research, AHRQ recently announced the funding of a coordinated set of projects to test different mechanisms for accelerating the health system's adoption of research findings that demonstrate ways to improve quality of care. These include financial incentives and rewards for providers, and innovative team-oriented educational programs. AHRQ also funds evidence-based practices to review the latest scientific evidence and draft summary reports such as a recent one on Blood Pressure Monitoring. The ACC urges Congress to support the work of the AHRQ and to provide a funding increase for AHRQ in fiscal year 2004.

CONCLUSION

Beyond better public awareness and the translation of research into practice, reducing the number of cardiovascular-related deaths is greatly dependent on research sponsored by the NHLBI. The ACC hopes the subcommittee shares its optimism and urgency about the unique opportunities that our scientists and clinical investigators now have to achieve their long-standing goal of conquering the nation's number-one killer. In summary, the ACC encourages the subcommittee to provide a funding level of at least $3.5 billion for the National Heart, Lung, and Blood Institute within the National Institutes of Health for fiscal year 2004. It is a wise investment in the future health of our nation.

PREPARED STATEMENT OF THE NATIONAL BREAST CANCER COALITION

INTRODUCTION

Thank you, Mr. Chairman and members of the Subcommittee for your dedication and leadership in working with the National Breast Cancer Coalition (NBCC) to help in our fight to eradicate breast cancer.

As you know, the National Breast Cancer Coalition is a grassroots organization dedicated to ending breast cancer through the power of action and advocacy. The Coalition's main goals are to increase federal funding for breast cancer research and collaborate with the scientific community to design and implement new models of research; improve access to high quality health care and breast cancer clinical trials for all women, and; expand the influence of breast cancer advocates in all aspects of the breast cancer decision making process. Nearly 600 NBCC advocates will be on Capitol Hill on Tuesday, May 6, to lobby their Senators and Representatives on a legislative agenda that reflects these goals. NBCC truly believes that with our extraordinary determination and unbelievable spirit, combined with your continued support for high quality breast cancer research, this deadly disease will someday be eradicated.

CONTINUED FUNDING FOR BREAST CANCER RESEARCH IS CRITICAL

The Coalition would like to emphasize the advancements in breast cancer research that have come about as a result of your longstanding support for this issue. Developments in the past few years have begun to offer breast cancer researchers fascinating insights into the biology of breast cancer and have brought into sharp focus the areas of research that hold promise and will build on the knowledge we have gained. We are at a point where we are now able to target genes and begin to know how to address one woman's breast cancer in a different way from another woman's. This knowledge is leading us forward in finding the answers to prevention of breast cancer, as well as how to detect it earlier, and treat it more effectively. Now is precisely the time to continue your support for this important research.

THE BREAST CANCER AND ENVIRONMENTAL RESEARCH ACT

NBCC asks for your support for increased appropriations for breast cancer research at the National Institute of Environmental Health Sciences (NIEHS). During the 107th Congress, Senators Chafee, Reid, Hatch and Leahy introduced S. 830, the Breast Cancer and Environmental Research Act. (Representatives Lowey and Myrick introduced the House companion bill, H.R. 1723.) This legislation will be reintroduced in the 108th Congress with the goal of establishing Breast Cancer and Environmental Research Centers at the National Institute of Environmental Health Sciences to support research on environmental factors that may be related to the etiology of breast cancer.

It is generally believed that the environment plays some role in the development of this disease, but the extent of that role is not yet understood. NBCC believes that a strategy must be developed and more research done to determine the impact of the environment on breast cancer. It is only when we understand what causes this disease that we will have a better idea of how to prevent it, how to treat it more effectively, and how to cure it.

Women want to do all they can to reduce their risk of breast cancer or a recurrence. However, little is known about how the millions of environmental exposures we encounter each day impact the incidence of breast cancer. While there have been isolated studies looking at the suspected environmental links to breast cancer, overall, the issue of what causes breast cancer and the association between the environment and breast cancer has been chronically underfunded and understudied.

The Coalition believes the Breast Cancer and Environmental Research Act is the appropriate strategy to examine this question. Many Members of Congress from across the political spectrum agree with this approach as well. NBCC specifically appreciates this Subcommittee's recommendation in CR 107–84 regarding the need for additional research in the realm of breast cancer and the environment. We thank the Subcommittee for taking these important first steps in endorsing the goals set forth in this legislation. The time is right for the Committee to move forward in the fight to eradicate this disease by providing $30 million to fund up to eight breast cancer and environmental research centers, which would make grants using a peer review and programmatic review process that involves consumers. NBCC urges the Committee to use the tremendously successful Department of Defense (DOD) Peer-Reviewed Breast Cancer Research Program (BCRP) as a model for the structure of this research program.

ACCOUNTABILITY AT NIH

Finally, NBCC believes the issue of accountability at NIH is an especially timely one with respect to the completion of doubling the NIH budget. We would like to see collaboration among consumer advocates, NIH and Congress, to create mechanisms to ensure a higher level of accountability for federally funded breast cancer research. The National Breast Cancer Coalition understands that the level of funding is meaningless unless the funds are allocated appropriately.

The Coalition believes that the call for increased accountability should be a collaborative effort, and wants to work with the Committee and with NIH and NCI. The Programmatic Review Group (PRG), which Dr. Klausner convened in 1998 to provide an account of NCI's plan to eradicate breast cancer, was a good beginning; however, a more comprehensive strategy is necessary.

We know that NIH and NCI are as committed as we are to finding prevention and cures for this disease. However, there needs to be outside oversight of NIH to monitor this process. NBCC believes that it is inappropriate for a government agency to design its own oversight; rather, the public must design and participate in a process that can review decisions without bias. The time is right for Congress to request an independent audit of research funding at NIH—using breast cancer re-

search funding as a model. The question of whether changes may be needed in the grant mechanism and research structure at these Institutes should be explored. This outside evaluation is necessary to update processes or to uproot outmoded or duplicative efforts that no longer make sense.

The Coalition also seeks answers to the questions that remain. For instance, how is breast cancer research funding currently being spent? Who sets priorities and what criteria are applied? And, how can we, as consumer advocates, seek to influence how the money is being spent?

NBCC believes that some of the answers to these questions lie in the model of accountability in the Department of Defense (DOD) Army Peer-Reviewed Breast Cancer Research Program (BCRP). While the DOD BCRP is significantly smaller and more focused than NCI and NIH, it has an effective infrastructure of accountability that serves as a good model for other research programs to follow.

The DOD Integration Panel has outside members that include advocates on both levels of peer and programmatic review. Also, the DOD Breast Cancer Research Program has reported the progress of the program to the American people during two public meetings called the "Era of Hope." These meetings have been the only times a federally funded program reported back to the public in detail not only on the funds used, but also with regards to the research undertaken, the knowledge gained from that research and future directions to pursue. These meetings allowed scientists, consumers and the American public to see the exceptional progress made in breast cancer research through the DOD Peer-Reviewed Breast Cancer Research Program.

As we are all aware, these are taxpayer dollars. We owe it to all of our constituencies to assure them that this investment is spent wisely. The National Breast Cancer Coalition supports increased appropriations for breast cancer research so that we can eradicate this disease as soon as possible, however, it is vital that the public understand how the funds are being spent. NBCC would like to work with Members of this Subcommittee on this issue.

CONCLUSION

Chairman Specter, Senator Harkin, and members of the Subcommittee, thank you again for the incredible investment you have made in helping us work to eradicate breast cancer. NBCC looks forward to continuing to work with you to end this disease.

PREPARED STATEMENT OF THE NATIONAL COALITION FOR HEART AND STROKE RESEARCH

My name is Jack Owen Wood. I solicit your support for more aggressive federal funding for research into prevention and treatment of the sister diseases, stroke and heart disease. Strokes and heart attacks are occurring at an alarming rate.

I am representing the National Coalition for Heart and Stroke Research. The coalition consists of 19 national organizations representing more than 5 million volunteers and members united in support for increased funding for heart and stroke research. Members of the Coalition include:

American Academy of Neurology; American Academy of Physical Medicine and Rehabilitation; American Association of Neurological Surgeons; American College of Cardiology; American College of Chest Physicians; American Heart Association; American Neurological Association; American Stroke Association; Association of Black Cardiologists Citizens for Public Action on Blood Pressure and Cholesterol, Inc.; Compliment; Congress of Neurological Surgeons; International Society for Cardiovascular Surgery; Mended Hearts, Inc.; National Stroke Association; North American Society of Pacing and Electrophysiology; Society of Interventional Radiology; Society of Vascular Surgeons; and WomenHeart.

I will deal primarily with one man's personal experience with stroke and its functional and financial costs—my own. I have only the use of my right arm.

I was born in 1937, raised in Vicksburg, Mississippi, earned an engineering degree at Mississippi State University and currently reside in Port Orchard, Washington. I worked for the Boeing Company in Seattle, am a former Director of the Washington State Energy Office, served as Director of Cost and Revenue Analysis and as the Forcasting Manager for a major Northwest Area Natural Gas Utility until May 1, 1995.

On May 1, 1995, at the age of 57, I was stricken and severely disabled by my stroke. Two years later I experienced a triple bypass heart operation. You might say I've "been there and done that" for both major cardiovascular diseases. So you see, I am an expert.

Several years ago I was offered an exciting and rewarding volunteer opportunity. I was asked to lead the "Jack Wood Stroke Victor Tour" for the American Heart Association.

The Jack Wood Stroke Victor Tour was a 5-state lobbying tour. Through it I tried to meet personally with every Northwest Congressional representative on his or her home turf (in Alaska, Idaho, Montana, Oregon and Washington). In each meeting I was joined by local people, stroke survivors and their families and medical professionals. I told my story and asked them to join the Congressional Heart and Stroke Coalition and to support increased federal heart and stroke research funding.

I am proud to say I traveled to 18 communities and met personally with 28 members of our delegation or their staff. Nearly half of our congressional delegation is now members of the Congressional Heart and Stroke Coalition.

One of the most powerful memories for me was the frequency in which Members of Congress or staff members related their personal experience with stroke. One member I spoke to lost both parents to stroke. I suspect many of you have stories too.

I realize your interest is greater than the physical impact of my stroke. Your concern must include the financial impact, not only to me, but also on our country from increased health care costs and lost productivity and its many implications.

I have confronted the difficult and painful task of calculating that cost to me. Besides being a man whose stroke took his ability to pick up and play with his grandchildren, his livelihood, and marriage, I remain a statistician at heart. I couldn't resist calculating and telling that part of my story. But please remember my story is not dissimilar to that of many of the 4.7 million stroke survivors in the United States. Many of whom were stricken in their prime earning years. Who in a matter of moments, seemingly without warning, are transformed from a contributor and provider to a receiver and patient.

Allow me to highlight three figures that I feel sum up my data and should be important to you. I estimate that my stroke at age 57:

—Reduced my earnings before retirement age 65 by over $600,000.

—Subsequently, the cost to the federal government in lost income and other taxes, early Medicare payments and Social Security disability payments is over $320,000.

—My HMO spent approximately $150,000 to respond to and treat my stroke.

—One man, over one million dollars.

About 700,000 Americans will suffer a stroke this year costing this nation an estimated $51 billion in medical expenses and lost productivity.

Earlier I described a stroke as occurring seemingly without warning. All too often as in my case, people either don't know or ignore the signs of a stroke, even one in progress. When my stroke hit I denied it. It took me two days after my stroke to acknowledge it and seek help. Because of research into new treatments, we now have tPA, a clot-busting drug, which if administered within 3 hours of the onset of stroke symptoms, can dramatically reduce the damage of clot-based strokes. Had I recognized and acknowledged my stroke, gone to a hospital with a neurologist on staff and had there been tPA, the impact of my stroke most certainly would have been lessened.

What is even more painful to me is that my impending stroke could have been detected. Unfortunately, we need to create easier and less expensive diagnostic techniques so that effective diagnostics can be given routinely as part of regular health exams. And they must be covered through insurance.

I am not asking for your sympathy. Instead, please think of me as two of the ghosts in the famous Dickens' story. Please don't misunderstand, I'm not casting you as Scrooge. See me as both the ghosts of things past and things yet to be. I too am here to tell you, the future, which I represent, needs not be. It is largely up to you.

I hope my story and estimate of the cost of my stroke convinces you that taking on stroke and heart disease through increased research, leading to better prevention, diagnosis and treatment is fiscally responsible. The human and financial costs are astronomical.

Thank you for your past support of research. I appreciate the support of Congress in the past for eliminating restrictions on access to rehabilitation services essential to those who have experienced a stroke. Unfortunately, caps on reimbursement will be re-implemented in July. I urge you to act on this important issue.

Prepared Statement of the American Society for Microbiology

The American Society for Microbiology (ASM) strongly recommends continued strong growth for the National Institutes of Health (NIH) to sustain and expand on

the extraordinary progress in medical research that has been set in motion during the past 5 years as a result of the substantial increased funding provided by Congress for the nation's biomedical research enterprise. The Administration has proposed $27.9 billion for the NIH in its fiscal year 2004 budget request, an increase of $549 million over fiscal year 2003 funding. The 2 percent increase is greatly inadequate and will undoubtedly decrease and slow promising areas of biomedical research. The ASM recommends that Congress approve a 10 percent increase in the fiscal year 2004 budget for the NIH to bring the level of funding to $30 billion. A 10 percent increase for the NIH budget will improve its ability to capitalize on the substantial achievements of the past 5 years and enhance its ability to seize scientific opportunities to advance national health and security.

Fortunately, the robust levels of budgetary support for the NIH over the past 5 years have produced medical and technological advances that serve public health as well as the defense of the nation and the world. These significant benefits include discovery of the mechanisms by which anthrax toxin destroys cells, which will speed development of anthrax therapies; the finding that available doses of licensed smallpox vaccine can be "stretched" by dilution to provide protection for more people; collaborative efforts to develop a new and safer smallpox vaccine; and new anthrax vaccine candidates that will soon enter clinical trials. NIH has also been responsible for a number of improved HIV/AIDS treatments, vaccines against pneumococcal disease and hepatitis A and B, potential vaccines against the West Nile and Ebola viruses, and genomic sequencing of more than 60 medically important microbes, including the bacteria that cause tuberculosis. Significant health challenges remain for the 21st century to find treatments and preventions for microbial threats worldwide. NIH plays a pivotal role in research efforts to combat old and new infectious diseases that undermine health and well being and cost this country more than $120 billion annually. The multiple threats of emerging, re-emerging, and drug-resistant infections mandate increased biomedical research.

The ASM, representing more than 42,000 members in the microbiological sciences, is particularly concerned with the threat from infectious diseases and bioterrorism in the United States and worldwide. The proposed fiscal year 2004 NIH budget includes $4.3 billion for the National Institute of Allergy and Infectious Diseases (NIAID), an increase of $354 million over the fiscal year 2003 request. The NIAID supports research and training on all aspects of infectious diseases, their causative agents and transmission, host responses to infection, advanced therapeutics and vaccines, and rapid diagnostic technologies. The NIAID over the past five years has contributed greatly to U.S. public health; for example, an impressive reduction in blood-transfusion transmission of HIV and hepatitis viruses, a 70 percent reduction in AIDS-related deaths since 1995, and the near eradication of Hemophilus influenzae infections in children.

BIODEFENSE RESEARCH

The nation looks to the NIH and to the NIAID for safe and effective countermeasures against biological agents to defend against bioterrorist attacks. This threat presents urgent challenges and new responsibilities for the biomedical community and heightens the importance of NIAID supported research on the rapid diagnosis, prevention and treatment of potential agents of bioterrorism. The ASM supports the fiscal year 2004 NIH budget request of $1.6 billion for biodefense research resources. The NIAID has a strategic plan and research agenda for potential agents of bioterrorism, which has been developed in collaboration with experts in the scientific community. The plan builds on NIAID funded biomedical research programs that hold promise in the defense against bioterrorism and against naturally occurring deadly infectious diseases. The NIAID is mounting an historic initiative to bring the full capability of science to bear on advances in knowledge and products to counter biological pathogens. NIAID expertise used with great success against conventional disease outbreaks will significantly enhance the effort to combat bioterrorism, and vice versa. This response to bioterrorism will require a long-term dedication of financial resources and scientific talents.

In his recent State of the Union address, President Bush proposed implementing a new initiative against biological warfare, Project Bioshield. This comprehensive plan calls for a more rapid development of state-of-the-art drugs and vaccines to target biothreat agents. Project Bioshield is intended to nurture cooperation among NIAID researchers, medical experts, and private industry to form a more focused counterterrorism defense. The Secretary of Homeland Security and the Secretary of Health and Human Services will collaborate to identify the most critical research needs. The Director of NIAID will have increased authority and flexibility to award

grants for the research and development of high-priority defenses such as next-generation smallpox vaccines.

Although the NIAID has always worked to protect Americans against infectious diseases, current global and domestic affairs have forced the Institute to reevaluate and refocus its considerable expertise. Its efforts against biothreat agents have been and will continue to be rooted in solid scientific evidence acquired through basic research. But the expedited translation of basic research findings into practical-use interventions has become more central to NIAID's mission. NIAID investigators will approach potential agents of bioterrorism with new, more efficient strategies, such as the development of broader-spectrum therapeutics and vaccines. More productive cooperations with biotechnology and pharmaceutical companies likewise are expected to streamline the development of countermeasures. The NIAID plan against bioterrorism comprises two complementary components: basic research on the biology of potential microbial agents and the mechanisms of host response to infections, and applied research for the development of new or improved diagnostics, vaccines, and therapeutics.

Biodefense research is the first priority for the program increases within the proposed fiscal year 2004 budget. The NIAID is supporting more than 50 initiatives in biodefense research. In fiscal year 2004, it expects to add 17 new and expanded initiatives, including the acquisition and storage of standardized reagents and other materials related to the study of Category A, B, and C priority pathogens, for eventual use by investigators and laboratories engaged in biodefense research. Also in fiscal year 2004 NIAID will refocus on current immunology and genetics programs that might provide information useful against biothreat agents. This includes the Pathogen Functional Genomics Resource Center and a to-be-established Cooperative Centers for Translational Research on Human Immunology. Other planned fiscal year 2004 initiatives include developing novel therapeutic strategies for blocking the effects of the botulinum toxin.

INFECTIOUS DISEASE RESEARCH

Bioterrorism threats should not diminish the NIH/NIAID mission to detect, prevent and control infectious diseases. Globally, infectious diseases are the leading cause of death, killing an estimated 14.9 million per year. In the United States infectious diseases cause millions of illnesses and cost the economy billions of dollars, despite our relatively high public health standards. We cannot be complacent about infectious diseases because of the persistence or re-emergence of old diseases and the emergence of new ones such as hantavirus, West Nile virus, which has spread to 39 states infecting thousands of people, Hepatitis C virus (HCV), which has infected almost 4 million people in the United States and about 9,000 people die annually from HCV, and Severe Acute Respiratory Syndrome (SARS), an atypical pneumonia of unknown etiology that has caused approximately 60 known deaths to date. There also is growing evidence that infectious agents cause or contribute to many chronic diseases and cancers. Antimicrobial resistance represents a major threat to increased mortality and morbidity from untreatable disease and the risk from the spread of drug-resistant pathogens.

Infectious diseases represent a global risk for nations and individuals. There is greater risk that Americans overseas will become exposed to serious infectious diseases like SARS, and international travel can serve as a mode of disease transmission. The NIAID has a long-standing commitment to stop the principal international killers like HIV/AIDS, tuberculosis, and malaria. The heaviest medical and economic burdens from these diseases exist outside the United States, but they endanger this country as well. Of the estimated 40 million HIV-infected persons worldwide, over 70 percent live in sub-Saharan Africa. Yet the United States has its own challenges: The annual number of new cases is not declining and perhaps one-third of those living with HIV/AIDS are unaware of their infection. The NIAID has in place a global research plan against these infections that includes significant research funding inside and outside the United States and the creation of strong alliances with foreign and international health organizations. This funding continues to produce promising candidate vaccines for prevention and therapeutic intervention, as well as breakthroughs in understanding HIV biology and host immune responses. The Administration recognizes the strategic importance of halting the HIV pandemic, evidenced in its fiscal year 2004 budget request to fund the Emergency Plan for AIDS Relief, a five-year, $15 billion initiative that triples international HIV/AIDS funding.

Tuberculosis and malaria have been health disasters for centuries of human history. The emergence of antimicrobial-resistant strains of these pathogens, aided by increased global travel and trade, have made it difficult to stop these diseases.

Among the world's populations, 16.2 million currently have active tuberculosis while malaria strikes an estimated 300 to 500 million new victims each year. If governments do not learn how to better control tuberculosis, by 2020 an additional 1 billion persons worldwide will be newly infected and 35 million of those will die, according to World Health Organization estimates. The NIAID estimates that 10 to 15 million in the United States currently have tuberculosis, and the Institute invests heavily in research on diagnostics, therapeutics and vaccines. Using a newly developed strain of tuberculosis bacterium that carries a mutated gene, NIH-funded scientists in the United States and India are learning how the pathogen protects itself and how it stimulates inflammation. In fiscal year 2002 the NIAID established the Millennium Vaccine Initiative to search for novel vaccines against tuberculosis and malaria. Although the latter disease remains relatively rare in this country, malaria around the world causes an estimated 300 to 500 million new cases and more than 1 million deaths each year. There still is no malaria vaccine, but NIAID-supported research has accelerated vaccine development.

Global events can also affect the threat from newly emerging infectious diseases, whether through travel or trade that carries pathogens from place to place. In the past few years, several frightening diseases have found their way into various human populations, including neurodegenerative disease caused by transmissible spongiform encephalopathies (TSE, e.g., "mad cow disease"), West Nile virus (WNV) infection, hantavirus infection and SARS. There will certainly be more of these unexpected outbreaks, as new microorganisms evolve and old ones develop greater virulence through resistance to standard drug therapies. NIAID research encompasses these and other emerging diseases, within strategic plans designed to anticipate more mysterious infections in the future. The NIAID is supporting WNV vaccine development and participates in the Interagency Task Force on West Nile Virus established in 2002. Studies at NIAID suggest that TSE diseases may be more widespread than believed, and scientists there plan future studies to understand its transmission from animal species to humans.

New infectious diseases attract headlines, but less dramatic diseases cost excessively in lost human and economic resources. NIAID resources are also needed to address "everyday" diseases such as hepatitis, sexually transmitted diseases, and food- and water-borne illnesses. The NIAID has made significant investments to blunt the impact of these and similar diseases, which account for many millions of illnesses each year. For example, there are an estimated 15 million new U.S. cases of STDs annually. NIAID-supported researchers have, among other discoveries, recently determined that the bacterial agent of gonorrhea binds to different molecules in the male and female genital tracts. Such detailed understanding of microbial biology and pathogenesis traditionally leads to successful therapies and prevention strategies. In 2000 an estimated 2.1 million people died worldwide from diarrheal diseases, often transmitted through food and water. At NIAID, development of a vaccine against rotavirus, a major cause of diarrhea in children, is a high global health priority.

The recently released Institute of Medicine report, "Microbial Threats to Health: Emergence, Detection and Response," reports that "Today's outlook with regard to microbial threats to health is bleak on a number of fronts. AIDS is out of control in much of sub-Saharan Africa, India, China and elsewhere; bioterrorism has become a reality; the relentless rise of antimicrobial resistance continues . . . microbial threats present us with new surprises every year." Research is the underpinning of the nation's capacity to prevent and control infectious diseases. A strong, stable biomedical research and training infrastructure is needed to investigate the mechanisms of molecular pathogenesis, or the cause of infectious diseases, the evolution of pathogeneses, drug resistance, and disease transmission. Fundamental scientific knowledge is needed to design new vaccines, discover new classes of antimicrobial compounds and devise new preventions and treatments for infectious diseases.

The ASM urges Congress to add 10 percent in fiscal year 2004 to the doubled budget of the NIH to bring the total to $30 billion. Continued, sustained investment in NIH and NIAID is critical to dramatically reduce the threat from both naturally occurring infectious diseases and intentional use of biological agents.

PREPARED STATEMENT OF THE UPPER COUNTY BRANCH, MONTGOMERY COUNTY, MARYLAND STROKE CLUB

A STROKE SURVIVOR: A PERSONAL STORY

Hello. My name is Susan Emery. I am the presiding officer of the Upper County Branch of the Montgomery County Stroke Club and I'm a stroke survivor.

Our club conducts education and support activities for stroke survivors, their family members, and caregivers. We serve people in the Maryland suburbs of Washington, DC, and are fortunate to be in the same county as the National Institutes of Health. We have benefited on many occasions by the participation of NIH staff members in our membership meetings. They have been generous in sharing information about their research into stroke prevention and treatment with us.

On December 26, 1965 at the age of nine, I was playing a new game with my brother and a few friends at the kitchen table. That's the last thing that I remember. I was unconscious for the next two days. My mother first learned, incorrectly, that I had spinal meningitis. I was transferred to another hospital where my mother was told that I had little chance of survival. Yet I'm here, more than 36 years later, and I've survived a stroke.

People seldom associate strokes with children. These strokes are rare, but they do happen. There are about three cases of stroke per year in every 100,000 children under age 14. One of the difficulties in dealing with strokes in children is getting the right diagnosis quickly. There are often delays in diagnosis of childhood stroke.

I spent two weeks in the hospital and the following four months in intensive physical therapy. My tenth birthday was spent in the hospital, and I have a picture in my photo album of myself with my mother and a new friend. My right eye is turned down, my mouth is turned down, but I'm still smiling. During the four months in therapy at Holy Cross in Detroit, I learned the basics: how to walk, how to talk, and how to move the fingers on my right hand. My mother followed the doctor's instructions and sent me back to school very quickly, where classmates helped me button and unbutton my coat and carry my books, and teachers taped papers to the desk so I could learn to write again. I survived that four months, and would never wish to repeat it.

I've been in therapy six times in my life. I need to tell you about the one time that was the most important to my family. I was 26 years old and had just had my first child. I kept her safe, for I knew my limitations. I always used my left hand to support her. But when she was six months old, she got to be a little heavy, and twice, as I was putting her on the floor to change her diaper, my right hand slipped from under her buttocks. She fell only inches in both cases and didn't even notice. But I noticed. I went in for two or three months of therapy close to Denver, Colorado, where I was living at the time. Here for the first time, they helped my right hand and arm dexterity through occupational therapy. I also learned that I had aphasia—the inability to speak, write or understand spoken or written language because of brain injury—because I called things like cornucopias, unicorns instead of fruit baskets. Instead of the word being the same, I picked a word that sounded the same. These therapists in Colorado worked with my mind and my body and I will forever be in their debt.

Close to fourteen years ago, I made a new life for myself in Maryland. Here, I've been an outpatient at the National Rehabilitation Hospital three times: once for my right foot, once for my Achilles tendon and once for my right knee. I've seen numerous physiatrists, all of whom are excellent in their field. I've also seen my fair share of therapists. Since I've had therapy off and on for most of my life, I can honestly say that the first few times you go in to see a therapist, you'll come out hurting more than when you went in. But in the long run, they help tremendously.

On a work related note, I received a Bachelor of Science in 1978 from Michigan State University in Computer Science and worked for 12 years in the field. I started working in the telecommunications industry in 1990, and got a Master of Science from the University of Maryland, University College in Telecommunications Management. I now work for ITT Industries as a senior engineer on a contract supporting the Federal Aviation Administration's leased telecommunications activities, and have worked there for more than five years. I've done more than survive. I've become a productive member of society.

Stroke research has changed my life. Without the research carried out 40 to 50 years ago, I would not have benefited from electric shock therapy that made me understand the muscles that moved my fingers. Without research done 30 years ago, I may not have been able to understand how to exercise my hand for dexterity. Without research performed ten years ago, the people around me would not understand that they need to get me to the hospital quickly if ever I have another stroke.

Without current support, researchers may never understand how to stop strokes before they happen or how to make current stroke survivors live healthier lives.

Stroke remains America's No. 3 killer and a major cause of permanent disability. About an estimated 4.7 million Americans live with the consequences of stroke and about 1 of 4 is permanently disabled. Yet, stroke research receives a mere 1 percent of the National Institutes of Health budget. I strongly urge you to significantly increase funding for the National Institutes of Health-supported stroke research, particularly for National Institute of Neurological Disorders and Stroke-supported stroke research. NIH stroke research is essential to prevent strokes from happening to children and adults in the first place, and to advance recovery and rehabilitation of those who survive this potentially devastating illness.

PREPARED STATEMENT OF MENDED HEARTS, INC.

I am Robert H. Gelenter, the legal representative for the Mended Hearts Inc, a national heart disease patient support group of 25,000 members across the country. We visit patients in about 450 hospitals throughout the United States. I have been appointed by the group to assist in this lobbying effort—a volunteer position.

More than 27 years ago, I was diagnosed with a rare heart disease. After having severe chest pains and trouble breathing for more than two years, I was diagnosed with hypertrophic cardiomyopathy, a disease in which the heart enlarges. The heart muscle eventually thickens so much that it can't pump blood effectively and does not grow in the normal parallel patterns. More than 36 percent of young athletes who die suddenly die from this disease. But, it affects men and women of all ages. It is sudden and one of the things known about this disease is sudden cardiac death. There is no cure for this disease. Medication may work and there is surgery that may or may not alleviate the pain. If that doesn't work a patient may need a heart transplant, yet spare organs are scarce. The doctor who made my diagnosis was trained at the National Heart, Lung, and Blood Institute of the National Institutes of Health.

Initially, I received several medications which allowed me to engage in most activities. But, some activities, such as walking up hills, gave me problems like shortness of breath and severe chest pains. But, generally I could function normally. However, after about 11 years, the discomfort was increasing, and it became apparent that I was in serious trouble. I could not walk sixty feet without having to stop to catch my breath. Sometimes the pain was so great that I would almost double over in the middle of the street. My wife told me that my face would become gray. The perspiration would pour off by body. If I was lucky I could find a chair to sit on. The quality of my life had deteriorated so drastically that I knew I needed some treatment.

Finally in 1988, I went to Georgetown University Medical Center for an angiogram—the gold standard for diagnosing heart problems. The cardiologist who performed the angiogram told me that he had bad news and worse news. The bad news was that I had a 95 percent blockage in my left anterior descending heart artery—the so-called "widow makers spot." The worse news was that I had a major chance of having a major heart attack with a less than a 5 percent chance of surviving that heart attack because of the hypertrophic cardiomyopathy. At this point, my wife was quietly crying and I was perspiring profusely. Since Georgetown University Medical Center did not have the expertise to operate on me, they called the NIH to see if they would accept me as a patient. I was sent home pending notice from the NIH.

My parents begged me to go to New York or San Francisco for second opinions. But, I knew that I had run out of alternatives. No matter what the result, I needed treatment and I needed it immediately.

I was accepted by the NIH. After entering the National Heart, Lung, and Blood Institute on February 6, I was operated on February 11, 1988. No matter how trite the expression—that was the first day of the rest of my life. The surgery, considered drastic and rare, is still considered the gold standard throughout the world for the treatment of hypertrophic cardiomyopathy. The Murrow Procedure, in honor of the creator, was developed and improved at the NIH.

Although this surgery is no longer performed at the National Heart, Lung, and Blood Institute, there is another experimental ongoing protocol in which the same effect is being attempted by using alcohol to deaden the excessive heart tissue.

Now, I am on medication for the rest of my life. My condition is progressive. Seven years ago, I was fitted with a pacemaker to insure that my heart beats at the correct rate. I am 100 percent dependent on this pacemaker. Without the pacemaker, there are times when my normal heart beat is so slow that I would die.

I am eternally grateful to the physicians funded by the National Heart, Lung, and Blood Institute, particularly to Dr. MacIntosh and his staff, for the gift of life. Because of this marvelous research supported by the NHLBI, I have lived 15 years pain free. I have seen two children graduate from college and three grandchildren born, I have shared these years with a wonderful wife. I have been able to work at my profession—an attorney at law.

I have had the gift of life restored to me. So to express my gratitude for that gift, I visit patients recovering from heart episodes at two hospitals, Washington Hospital Center and Washington Adventist Hospital.

I ask for an fiscal year 2003 appropriation of $3.5 billion for the NHLBI, including $2.1 billion for its heart disease and stroke-related budget.

My experience is the proof that the research supported by the National Heart, Lung, and Blood Institute benefits not just the patients at the NIH Clinical Center, but throughout the United States. The benefits go worldwide as well.

Heart attack, stroke and other cardiovascular diseases remain the No. 1 killer and major cause of disability of men and women in the United States. Nearly 40 percent of people who die in the United States die from cardiovascular diseases. This year, nearly 950,000 Americans will die from cardiovascular diseases, including almost 150,000 under the age of 65.

Thank you for your support of National Heart, Lung, and Blood Institute's heart research.

DEPARTMENT OF EDUCATION

PREPARED STATEMENT OF THE NCB DEVELOPMENT CORPORATION

On behalf of NCB Development Corporation, I am pleased to submit written testimony to the United States Senate's Committee on Appropriations Subcommittee on Labor, Health and Human Services and Education on the subject of charter school facility finance. I am Terry D. Simonette, president and chief executive officer of NCB Development Corporation located in Washington, District of Columbia and I would like to thank Chairman Specter for the opportunity to submit this written testimony today on fiscal year 2004 funding for Charter School Facility Finance which addresses the needs of the underserved and displaced communities under the jurisdiction of the Subcommittee. At the outset, let me share with you some background information on NCBDC and our approach to address the charter school facility finance problem. Then I would like to share our thoughts on why charter schools could be easily looked at as community development strategy.

NCB Development Corporation (NCBDC) was founded as a 501(c)(3) non-profit affiliate of the National Cooperative Bank pursuant to the National Consumer Cooperative Bank Act (Public Law 95–351). NCBDC is a national mission-driven nonprofit organization that for 25 years has provided innovative financial and development services to improve the lives of low-income individuals, families, and communities. By creatively investing in our neighborhoods, advocating elected officials around public policy, and collaborating with other national and local community-based organizations, NCBDC helps charter schools finance and develop facilities; creates a policy environment that supports strong, self-sustaining communities; enables community health centers to expand to serve more patients; preserves and creates affordable housing; and helps socially responsible businesses thrive.

NCBDC's solutions are based on the cooperative principles of self-help, democratic control, and open participation. NCBDC targets community needs nationwide that have not been adequately addressed by traditional approaches. In its 25 years of existence, NCBDC has grown from a provider of high-risk development finance to a multifaceted national organization engaged more broadly in pursuing solutions to some of the most urgent problems facing under-served communities today.

Mr. Chairman, as you may already know, there are currently about 2,700 charter schools in 36 states and the District of Columbia, giving nearly 684,000 children an opportunity to receive a quality education. Unlike traditional public schools, charter schools are not given a public building in which to operate. Instead, it is up to the charter school to find and fund an appropriate location. Operators, who are often concerned parents, teachers, or nonprofit organizations, typically have little experience with planning, zoning, and building code regulations, let alone finding affordable space and adequate financing. And very few financing organizations are willing to lend to charter schools.

Since the mid-1990's, NCBDC has been considered an expert in the small community of organizations in the forefront of designing and implementing innovative financing strategies to meet charter schools' demand for capital. To date, between our

lending and technical assistance programs, NCBDC has assisted over 200 schools in 17 states, provided more than $30 million in facilities financing, and helped leverage more than $100 million in additional funds. Major partners in these initiatives have included the U.S. Department of Education, the National Charter Schools Alliance (formerly Charter Friends National Network), the Florida Consortium of Charter Schools and the Midwest Charter Facilities Coalition.

In the initial round of the highly competitive U.S. Department of Education's Charter School Facilities Financing Demonstration Program, NCBDC partnered with The Reinvestment Fund, a leading community development financial institution based in Philadelphia, and Foundations, Inc., a leading technical assistance provider. We were successful in receiving a $6.4 million grant to create the Charter School Capital Access Program (CCAP). CCAP is in the process of creating a $40 million loan pool that will be leveraged with capital from investor types including banks and other financial institutions like PNC Bank located in Pennsylvania. This is a leverage ratio of nearly seven private dollars for every one public dollar. Through CCAP, we will focus on schools located in the Mid-Atlantic States including New York, New Jersey, Pennsylvania, Delaware, Virginia and the District of Columbia.

In addition, in partnership with the National Charter Schools Alliance (formerly Charter Friends National Network), NCBDC is a recipient of a U.S. Department of Education National Activities Grant that establishes a pilot program of on-the-ground technical assistance and workshops in facility development and financing. NCBDC's receipt of the grant is a testament to its combination of financing acumen and commitment to community revitalization. We are working with the Florida Consortium of Charter Schools and the Midwest Charter Facilities Coalition to provide professional support to charter schools seeking to develop new facilities. As part of the 18-month technical assistance program, NCBDC and its partners make available on-site resource specialists who are capable of providing assistance to charter schools in all aspects of facilities development and financing. On a national level we are working with grassroots charter support groups to conduct workshops around the country that help charter schools manage the challenges of facilities development and financing.

In the past six months, NCBDC has had the opportunity to provide technical assistance in Pennsylvania. In November 2002, NCBDC, along with The Reinvestment Fund, conducted training in Philadelphia on charter school facility financing, sponsored by the Northwest Regional Education Laboratory. In January 2003, NCBDC, again in partnership with The Reinvestment Fund, conducted a training given by the Pennsylvania Charter School Resource Center in Harrisburg, Pennsylvania, discussing charter school facilities financing and our new joint venture, the Charter School Capital Access Program or CCAP.

Because we have seen firsthand the dire need for charter school facility finance, NCBDC supports the continuation and expansion of the Charter School Facilities Financing Demonstration Program by increasing appropriations levels as authorized by the United States Congress in No Child Left Behind (NCLB or Public Law No. 107–110) signed by President George W. Bush into law on January 8, 2002.

A United States General Accounting Office (GAO) report "Charter Schools: Limited Access to Facility Financing" (GAO/HEHS–00–163, September 2000) states that facilities financing issues pose a formidable obstacle for the vast majority of start-up and established charter schools. Each of the three major financing approaches—municipal bonds, per pupil allocations, and conventional financing—offer only limited opportunities for charter schools that seek funds to lease, acquire, construct, or renovate a facility. There is no more serious challenge facing charter schools nationally than obtaining upfront and ongoing financing for facilities. Despite the difficulty in securing credit, charter schools are remarkably resourceful in addressing their facilities needs, yet are generally unable to take advantage of the financing that is available to school districts and typically pay for facilities out of their regular operating funds. As a result, finding and funding a building impacts limited operating funds which in turn impacts teachers, administrative personnel and the purchase of everyday supplies.

Not finding a suitable home has delayed school openings, and forced schools to scale back their programs or shut down altogether. According to the Center for Education Reform, a survey of 84 charter schools that never opened showed that 27 percent were due to the inability to find adequate facilities. Of 194 charter schools that were closed, 9 percent stopped operations due to facility issues. Charter schools are usually distinguished by their relatively small size, perceived instability of revenue streams, short operating track records, and political uncertainty. These characteristics pose formidable obstacles for the private sector, which has a low-risk tolerance and is often reluctant to lend in an "emerging" market. Consequently, charter

schools also require new, creative financial models to address their growing demand for capital.

NCBDC applauds the President and the United States Congress in their commitment to charter education. Following the fiscal year 2003 appropriations process, the President supported and the Congress passed legislation that provided $25 million dollars for the new Credit Enhancement for Charter Schools Facilities Program within the Department of Education's Office of Innovation and Improvement to assist charter schools in acquiring, leasing, and renovating school facilities. This is done through a competitive grant process to public and non-profit entities for loan guarantees, debt insurance, and other activities that facilitate private lending. Much like the Charter Schools Facilities Financing Demonstration Program, this program will award an estimated 3–5 awards to be given within a range of $2.5–$10 million.

While the demand for charter school facility finance is estimated nationally at $2 billion, $25 million falls far short of the $200 million authorized in No Child Left Behind, as outlined in the Carper-Gregg Amendment in the act. The bipartisan Carper-Gregg Amendment authorized substantial funding for the continuation and expansion of the demonstration program by providing not only $200 million yearly in grants to entities that help charters leverage private financing for facilities and start-up costs, but it also expanded the Public Charter Schools Program to provide $200 million in matching grants to states that establish or enhance programs of per pupil facilities funding assistance to charter schools.

With our long history of a strong commitment to community development, particularly as it relates to underserved urban populations, NCBDC believes that strong schools are a cornerstone of any thriving community. Good schools keep families involved in neighborhoods, and this involvement is essential to community revitalization. Public charter schools encourage stability by offering parents a tuition-free choice outside the traditional public school; charter schools can keep families in communities with under-performing public schools. In addition, NCBDC has found that in the process of developing a facility, charter schools can be an effective tool for urban renewal and neighborhood revitalization. Finally, NCBDC believes that strong school-community partnerships, which are encouraged by charter schools, help strengthen neighborhoods.

An example of a charter school that has affected the community around it is the Universal Institute Charter School, started by Universal Community Homes (UCH), in Philadelphia, Pennsylvania. UCH is a community development corporation that provides housing, economic revitalization, and training and social services to the area's low-income residents. UCH started the school due to unfortunately high rates of violence and disgraceful test scores in local public schools. In partnership with The Reinvestment Fund, NCBDC made two loans to the school. Together, NCBDC and The Reinvestment Fund provided more than $2 million in financing for the school's building, when it opened in 1999 and again in 2000 when it needed additional financing for expansion and renovations. Today, the Universal Institute Charter School is a Title I school, filled at maximum capacity, with a waiting list of more than 400 children. In March of 2003, its charter was renewed for another five years. The school has come to be considered an integral part of the community.

During this time of budget deficits and the rise in domestic security costs with the aftermath of war, fiscal constraints make efforts to fulfill Congress' commitment to education, especially charter school facility finance, far more difficult then it has been in years past. Charter advocates, including NCBDC, have long been supportive of the efforts by the Administration and Congress to provide adequate appropriations for the charter school facilities initiatives set forth in the landmark bipartisan NCLB. We are hopeful that this Subcommittee, and ultimately this Congress, will provide appropriate charter school funding at the authorized levels, as charter schools are continuously faced with the lack of funding or expertise to purchase, build, or renovate a building and other physical plant requirements.

NCBDC appreciates this opportunity to reinforce the critical need served by supporting expanded funding for charter school facility finance. With your assistance, the charter school community can continue to make a difference in the lives of our most vulnerable children, families, and communities. In summary, NCBDC requests a NCLB authorized fiscal year 2004 appropriation level of $200 million to help charters leverage private financing for facilities and start-up costs—an increase of $100 million over the President's fiscal year 2004 request and $175 million over the fiscal year 2003 appropriation level. In addition, NCBDC supports the continued expansion of the Public Charter Schools Program by supporting the President's request of $220 million to provide matching grants to states that establish or enhance programs of per pupil facilities funding assistance to charter schools.

Thank you again for allowing NCBDC to present its concerns regarding fiscal year 2004 appropriations provision of charter school facilities financing in testimony before the Subcommittee.

PREPARED STATEMENT OF AMERICANS FOR THE ARTS

REQUEST

Americans for the Arts is pleased to submit testimony in support of fiscal year 2004 appropriations at a level of $53 million for the Arts in Education program of the U.S. Department of Education (USDE).

Americans for the Arts is one of the leading national nonprofit organizations for advancing the arts and arts education in America. With a 40-year record of objective arts industry research, it is dedicated to representing and serving local communities and creating opportunities for every American to participate in and appreciate all forms of the arts.

As members of the Subcommittee know, the Elementary and Secondary Education Act provides that funding up to $15 million be directed to the John F. Kennedy Center for the Performing Arts and VSA arts. Prior to fiscal year 2001, funding never exceeded the floor level. Beginning in fiscal year 2001, however, Congress has consistently appropriated funding exceeding the floor in order to fund a broader array of arts education programs. For fiscal year 2003, Congress appropriated $33.7 million. This new funding has allowed the Department of Education to add three significant programs:

—a competitive grants competition to further develop established arts education models;

—support for professional development for arts educators in four arts disciplines; and

—a program establishing partnerships between schools and community cultural organizations to serve at-risk children and youth.

We ask the Subcommittee to appropriate $53 million for fiscal year 2004, with the bulk of the increase to be allocated to the Arts in Education Model Development and Dissemination Program, Professional Development training in music, theater, dance and the visual arts, as well as Cultural Partnerships for At-risk Children and Youth.

THREE REASONS TO INCREASE ARTS EDUCATION FUNDING

The reasons for increasing arts education funding are many and varied, but we will begin with the most important: arts education works for children. An increasing volume of research confirms that arts education has substantial beneficial effects in several areas, including but not limited to academic achievement. We refer the Subcommittee to a recent research compendium Critical Links: Learning in the Arts and Student Academic and Social Development, released by the Arts Education Partnership, which includes 62 separate studies pointing to "critical links" between arts education and reading, writing, mathematics, cognitive skills, motivation, social behavior, and the school environment. Of special importance, given USDE's core function of providing support to those most in need, the studies suggest that arts education may be especially useful for students in economically disadvantages and/or in need of remedial instruction. The arts sometimes succeed when everything else has failed.

The second reason is that schools desperately want it. Even now, when the accountability and testing regimens of the No Child Left Behind Act have focused schools' attention on what some call "the basics," many schools understand that the arts are a core academic subject, as stipulated by No Child Left Behind, that they are essential, and that they work. The Department of Education's first model grant competition generated overwhelming interest despite the tiny number of awards. A larger amount of funding, coupled with a smaller grant size, will at least begin to address the demand.

The third reason is that while there is tremendous interest in arts education, substantial improvements need to be made to delivery systems, including promoting cooperation and joint programming between community cultural organizations and schools for afterschool arts education programs for at-risk youth; better professional development training for arts teachers, artists, and classroom generalists; developing authentic and practical assessments of arts learning; as well as much more research on effective programs. USDE's model grants program aims to further develop established programs that improve arts education, to evaluate these programs, and to disseminate the results. Thus, it is absolutely in accord with a central prin-

ciple of the federal role in education: to find out what works and to disseminate this information to states and local school districts so that they may select and tailor programs to fit their own needs and circumstances. This is the reason that we urge the Subcommittee to recommend that funding include at least $1 million for evaluation and dissemination. We note that each of the projects funded under this program include a substantial research component. It is particularly important to add this modest amount of funding because the USDE's existing and planned research efforts, including the What Works Clearinghouse, do not include substantial work on arts education.

CASE EXAMPLE: MISSISSIPPI'S WHOLE SCHOOLS INITIATIVE

In order to show in more detail how the model grants program further develops programs for improving arts education, we turn to the Mississippi Whole Schools Initiative. In 2001, Mississippi's Whole Schools Initiative was awarded a $1 million grant from USDE's Arts in Education Model Development and Dissemination Program. The program's roots go back to 1991, when as a response to "back to basics" school reform and the lack of arts instruction in Mississippi, the Mississippi Arts Commission (MAC) commissioned a study of the Mississippi environment, appropriate national models and relevant research. The resulting paper called for a pilot program characterized by the involvement of every student and teacher in arts-infused learning; the integration of the arts into daily classroom instruction for all students; and sequential, comprehensive instruction for all students in dance, drama, visual arts, and music by certified arts specialists that would be documented and evaluated. The pilot program began in 1992.

In 1996, MAC and the Mississippi Alliance for Arts Education commissioned the Mississippi State University to conduct a survey on the status of arts instruction in Mississippi public schools. Among the findings: (1) one full-time music teacher for every 840 students, including high school band programs, (2) one full-time visual arts teacher for every 3,150 students, (3) one full-time drama teacher for every 17,848 students, and (4) one full-time dance teacher for every 31,235 students. Research conducted recently revealed that, in 1999, the ratios of arts teachers to students remain little changed.

The Whole Schools Initiative was launched in 1998 with a core belief that art is an essential part of every child's education, speaking to students in language that demonstrates concepts, reveals symbols, forges connections, and helps prepare them for life. It is the first comprehensive statewide arts education program in Mississippi. Its goals are to improve student academic achievement through infusing arts into the basic curriculum, to enrich students by increasing their skills and knowledge in all arts disciplines, to assist the professional and personal growth of teachers and administrators through arts experiences, to use the arts to increase parental and community involvement in schools and to assist schools in building a sustainable system for supporting arts infusion.

Not only does the program improve the quality of arts education being offered in participating schools, it is often the only chance that Mississippi children, in poorly funded schools and from families living below the poverty level, will ever have to receive any arts instruction. Nineteen of the 26 schools involved in the initiative serve student populations where 35 percent or more of the students qualify to receive free/reduced lunches, fourteen schools have at least 70 percent and seven schools have at least 90 percent.

Eleven schools involved in the initiative are located in rural communities and others serve them. Six of these schools have the lowest per pupil expenditure in the state. In 2001, the Commission responded to the critical teacher shortage and educational disparities in the Mississippi Delta Region by locating the summer institute in the Delta, recruiting Delta schools and partnering with Delta State University on pre-service and in-service training of teachers for this region. This weeklong institute serves to inform, empower and motivate school teams and gives them the tools to successfully infuse the arts into their school curriculum. Schools attend in teams of eight, including the principal, project director, classroom and arts teachers and a community representative. District superintendents are required to participate in a one-day program planned with their needs in mind. Attendance by this team and superintendent is mandatory in order to receive grant funds from MAC.

Twenty-six schools now participate in the Whole Schools Initiative, representing the economic, racial and geographic diversity of Mississippi. Each designs an arts-based, school-wide program, with a five-year strategic plan appropriate to its resources, demographics, philosophy, and school culture. MAC provides the tools necessary for planning and implementation and requires the inclusion of two essential components: the use of arts teachers and visiting artists in the areas of dance,

drama, music, visual art, creative writing and folk arts to strengthen the place of the arts as a core academic subject in its own right; and infusing the arts in all academic subjects in order to increase student success in these subjects. Each school receives grant funds, technical assistance, mentoring and professional development for six years, as long as it shows progress towards the goals of its strategic plan and re-applies to the grant program each year. The schools partner with various education and arts-based entities and other community resources to carry out the activities of the initiative. Partnerships include local arts councils, Institutions of Higher Learning, the Mississippi Alliance for Arts Education, professional artists, local school districts and art museums.

In 2001, the Whole Schools Initiative was one of eleven successful applicants for a grant from USDE's Arts in Education Model Development and Dissemination Program. This $1 million grant is allowing MAC to expand its role with universities, encouraging the development of pre-service courses that would strengthen arts infused instruction and aid arts majors in becoming effective instructional leaders. The grant will also enable MAC to expand and refine its evaluation model, a model based on both sociological and statistical data. A final component of the USDE funding will allow MAC to develop training materials and procedures that can be used to replicate the program in other settings. At the end of the three-year grant period, the project will "blueprint" a model built on a research base, field-tested in a diverse set of schools, evaluated internally and externally, and which has already produced substantive results.

This funding has made possible extensive professional development opportunities for teachers and administrators. More than 15,000 students and 800 educators benefit annually from activities at a weeklong summer institute, two retreats and field advisor visits. Other ways in which it is strengthening the program include a course for education majors that is being developed at the Delta State University, a "teacher friendly" and "teacher useful" interactive web site, and the designation of model schools in the north, central, and southern regions of Mississippi where the initiative's work may be observed.

Other states will benefit from the documentation and dissemination of the initiative. Many states have a strong interest in implementing this model but lack the resources, knowledge and experience to do so. States that have approached MAC and participated in the institute include New Mexico, Illinois, Kentucky, Florida, and Louisiana.

CONCLUSION

As the example of the Whole Schools Initiative demonstrates, federal funds boost the quality and quantity of support for arts education as well as the knowledge that can be gained and disseminated across the education establishment. Increased funding means more help for state departments of education and for educators in schools and cultural organizations, and most important, it means a better education for our children. We urge the Subcommittee to recommend $53 million in funding for the USDE's Arts in Education programs in order to allow more programs like Mississippi's Whole Schools Initiative to flourish.

PREPARED STATEMENT OF THE THURGOOD MARSHALL SCHOLARSHIP FUND

Thank you for allowing us this opportunity to submit written testimony on behalf of the Thurgood Marshall Scholarship Fund (TMSF). I am asking you to support a total request of $20 million in the fiscal year 2004 Labor, Health and Human Services, Education appropriations bill. This amount includes $10 million for TMSF's Capacity Building Program and $10 million for Technology Expansion Programs at Public HBCUs.

Thurgood Marshall Scholarship Fund represents 45 Public HBCUs and five historically black law schools located in 22 states, the District of Columbia and the U.S. Virgin Islands. TMSF is only national organization that provides merit scholarships, programmatic and capacity building support to the staff and students attending Public HBCUs. Currently 215,000 students attend Public HBCUs, and many of them are the first in their families to attend college.

To continue providing valuable and meaningful opportunities for so many deserving students, Public HBCUs must be prepared to provide students with an educational experience that prepares them for today's increasingly competitive and ever-changing world. TMSF member schools lack the financial resources to fully realize this mission. The National Capacity Building and Technology Expansion Programs for which we are seeking funding will help our schools to do so by focusing on developing student and faculty leadership, increasing technology, operations,

communications and staff and student expertise, and strengthening minority professional involvement with students in the areas of community service and career development. Just as importantly, increased outreach activities of Public HBCUs to high school guidance counselors and students will help assure that those in need are aware of and have access to opportunities available at Public HBCUs.

The National Capacity Building Program includes the following elements:

—*Leadership Development*.—Consists of two national training conferences for students attending Public HBCUs and the five public historically black law schools. This program will provide resume building, leadership training, strategic planning, community service, technology training and career development.

—*Member School Training and Development*.—A national program designed to provide training and development to the executive management team, faculty and staff at TMSF member colleges and universities in the areas of financial management, outreach, human resource management, and leadership development. The second component of the program is a series of regional training conferences that will link local businesses, state, county and city governments and nonprofit organizations with Public HBCUs to explore innovative partnerships to help HBCUs survive and grow.

—*Student Internship Placement Services*.—A program designed to provide training and development opportunities for placement officers from the 45 Public HBCUs by allowing them to interact with human resource officers from corporations, non-profit organizations, and federal agencies, and increasing information-sharing on career marketing.

—*National College Guide*.—Will provide for the development of a national college guide and on-line directory designed to increase college enrollment for minority students. The guide will feature financial aid resources, descriptions of the 45 Public HBCUs and a common application that can be used at any one of the TMSF member schools. The guide will be distributed to the nation's 14,000 public school districts.

—*Volunteer Training*.—This program is designed to engage diverse volunteers of all ages, race and religions in working with at-risk youth. The volunteers will provide mentoring and assistance in the areas of college enrolment, career planning and leadership development. A national volunteer training program will be designed and piloted with ten schools to mobilize 1,000 volunteers.

—*Post-Graduate Activism*.—A national program designed to organize and train graduates and students of Public HBCUs in the areas of career development and community service, including national training seminars to establish graduate and student councils to explore ways that Public HBCU graduates can leverage their workplace skills to benefit Public HBCUs. This program will be complimented by an interactive website.

—*Community Outreach Offices*.—This program will provide for additional support for the Mid Western Capacity Building Office and the establishment of an office in the South and Western States. These offices will work with local high schools to link students and parents with college attendance; work with the local and regional employers to link students from the areas with internship and job opportunities addressing the local and regional talent drain issues facing many communities.

—*National Counselor Training & Youth Outreach*.—The National Counselors Training program will design, produce and provide training to the middle and high school counselors at the nation's 17,000 school districts on opportunities at Public HBCUs. This program will be complemented by a web site where counselors can access applications to the 45 member colleges and universities along with tips on preparing families on how to support their children who may be the first to attend college.

—*Research*.—A national research program designed to collect and present the demographical data of the 45 Pubic HBCUs, this program will study student enrollment trends; private, pubic and individual giving trends by institutions; enrollment by race; enrollment by regions of the country; economic impact of the colleges and universities; tracking of the community impact of the schools; retention and recruitment rates.

The Technology Expansion Project is equally important, as illustrated in the following statistics:

—Two out of five Public HBCUs are in urgent need of upgrading their technical infrastructure.

—On only one out of forty-five campuses, do more than 75 percent of students own computers.

—Less than one-half of TMSF member school campuses have a moderate or high degree of sophistication providing IT and technical support staff.

—Forty percent of TMSF member schools reported that they require both additional computer hardware and software to conduct their Advancement programs.

This program will make resources available to 20 of our 45 member schools in the following areas:

Campus-wide Information Tracking System.—Development of an intranet for each institution to improve internal and external communication practices while ensuring consistency and eliminating duplication. The intranet will allow the sharing of critical contact information, which will in turn provide faculty with an efficient and effective means for sharing best teaching practices; thus improving the quality of Public HBCU students' educational experience.

Advancement Office IT infrastructure.—Twenty grants at an average of $50,000 each to improve internal capacity in the Advancement Offices. Grants could be used to upgrade hardware, software, Alumni tracking, web presence or similar programs within the Advancement office based on the individual needs of each school. These grants will be administered through an RFP process.

—*Information Technology Resource Center (ITRC)*.—The ITRC will establish and maintain a special website accessible only to member schools to share resources, files and ideas with the number of uses open to the creativity of the TMSF community. The ITRC includes the following components: distance-learning courses, a resource database, which can be used to monitor funding resources, technology developments and opportunities, and to disseminate information to public sources, strategic planning tools, a web-based forum for interactive sharing of resources and ideas, and continuing education for faculty and staff.

TMSF member schools are a critical source of higher education for African-Americans. Over two million alumni have graduated from TMSF member schools.

TMSF was created to bridge the technological, financial and programmatic gap between public and private HBCUs. Since our inception, TMSF has provided more than $20 million in scholarships and programmatic support to students attending Public HBCUs.

—Nearly eighty percent of all students enrolled in historically black institutions attend TMSF member schools.

—Ninety percent of all students attending Public HBCU's require some form of financial assistance.

—TMSF member law schools graduate more than fifty-six percent of the African-American lawyers in the nation.

—TMSF schools graduate more than fifty-eight percent of the African-American public schoolteachers across the country.

As a national resource, Public HBCUs supported by TMSF are committed to building the infrastructure and capacity to continue to support their students and to serve as instruments of economic growth in their states and across our nation.

In closing, I thank you for your past funding of TMSF, and urge you to support this request for additional funding that will allow us to carry out our important mission—*Preparing a New Generation of Leaders.*

PREPARED STATEMENT OF THE AMERICAN CHEMICAL SOCIETY

The American Chemical Society (ACS) would like to thank Chairman Arlen Specter and Ranking Member Tom Harkin for the opportunity to submit testimony for the record on the Labor, Health and Human Services, Education Appropriations bill for fiscal year 2004.

ACS is a non-profit scientific and educational organization, chartered by Congress, representing more than 161,000 individual chemical scientists and engineers. The world's largest scientific society, ACS advances the chemical enterprise, increased public understanding of chemistry, and brings its expertise to bear on state and national matters.

Federal investments in research and science education are critical to producing the technologies and scientific workforce that ultimately determine our economic and national security. As our economy becomes increasingly dependent on technology, the demand for scientists and engineers during the next decade is expected to increase at four times the rate for other occupations. Unfortunately, today's high school students on average lag well behind their European and Asian counterparts in math and science, and NAEP studies suggest that more than 82 percent of 12th graders are not proficient in science. To maintain U.S. technological leadership, the Department of Education must do more to improve teacher quality in math and

science and to provide incentives for all students—including underrepresented groups—to pursue degrees in these fields.

ACS is encouraged by the Department of Education's recent Mathematics and Science Initiative, which is aimed at reversing "waning federal attention to mathematics and science education" in recent decades. ACS has long supported a key goal of this initiative: to increase the number of science and math teachers who are well trained in the subjects they teach. Because research shows that subject knowledge is critical to effective teaching, it is alarming that nearly half of all science teachers did not major or minor in the field they are teaching.

We commend Congress for seeking to improve teacher quality and student achievement in K–12 math and science education by establishing the Department of Education's Math and Science Partnership program in the No Child Left Behind Act. This program, which is the sole source of dedicated math and science funding at the Department, was authorized at $450 million. Following scant funding in fiscal year 2002, we applaud Congress for boosting appropriations to $100 million in fiscal year 2003—a level at which the program becomes viable by allowing the advancement of merit-based partnerships across all states. ACS urges Congress to work toward the authorized level by funding the program at $200 million in fiscal year 2004. Increased investment will enable the types of innovative partnerships between school districts, university science and engineering departments, businesses, and educational organizations that can produce real gains in student achievement. We believe that partnerships that advance long-term, content-based professional development should receive priority in this program.

ACS recognizes that economic incentives can help draw students and provide opportunities for careers in math and science, including the teaching field. ACS supports the administration's proposal to increase the level of loan forgiveness from $5,000 to $17,500 for elementary and secondary education math and science teachers who teach in high need areas. Also, to provide graduate and doctoral students with enhanced fellowship opportunities, we support increased funding for the Graduate Assistance in Areas of National Need program. This program provides fellowships to assist graduate students with excellent records who demonstrate financial need and pursue the highest degree available in a field designated as an area of national need, including science.

In 20 to 30 years, the United States will be a majority minority country. We must redouble our efforts to ensure that the science and engineering educational and professional fields adequately reflect these changing demographics. To that end, the Society strongly supports the Department's Minority Science and Engineering Improvement program. This program, which provides grants to predominately 2- and 4-year minority-serving institutions, aims to significantly increase the number of underrepresented ethnic minorities, particularly minority women, pursuing science and engineering careers. The program received $8.5 million in fiscal year 2003, but additional funding is needed to reach the larger population necessary to achieve real gains in this area.

All students need the chance to succeed in an increasingly global and technology-driven society. ACS looks forward to working with Congress and the administration to improve teaching and learning in math and science.

PREPARED STATEMENT OF THE UNITED TRIBES TECHNICAL COLLEGE

Summary of Request.—For 34 years United Tribes Technical College (UTTC) has been providing postsecondary vocational education, job training and family services to Indian students from throughout the nation. Our request for fiscal year 2004 funding for tribally controlled postsecondary vocational institutions as authorized under Carl Perkins Vocational and Applied Technology Act is:

—$8 million under Section 117 of the Perkins Act, which is $1 million over the fiscal year 2003 enacted level. This funding is essential to our survival, as we receive no state-appropriated vocational education monies.

—Ensure that the provision in the fiscal year 2002 and 2003 Labor-HHS-Education Appropriations Acts that waived the regulatory requirement that we utilize a restricted indirect cost rate is continued.

—Funding for renovation of our facilities, many of which are original to the Fort Abraham Lincoln army installation. A recent study commissioned by the Department of Education shows a facility need for UTTC of $49 million.

Restricted Indirect Cost Issue.—The fiscal year 2002 and fiscal year 2003 Labor-HHS-Education Appropriations Act provided that notwithstanding any law or regulation, that Section 117 Perkins grantees are not required to utilize a restricted in-

direct cost rate. We thank you for taking this action, and ask that it be continued in the fiscal year 2004 Act.

In 2001, the Department of Education, for the first time, directed Indian grantees (both Sec. 116 and 117 grantees) to apply a "restricted indirect cost rate" to their grants. This means each tribal grantee must obtain another indirect cost rate—exclusively for its Perkins Act grant—from its cognizant federal agency (which in most cases is the Inspector General for the Department of the Interior.)

The Department gave two reasons for applying a restricted rate to these Perkins Act Indian programs: (1) The 1998 Amendments to the Perkins Act (Sec. 311(a)) prohibits the use of Perkins Act grant funds to supplant non-federal funds expended for vocational/technical programs. This "supplement, not supplant" limitation previously applied to State grants, only; and (2) A long-standing DoEd regulation (promulgated years before the 1998 Perkins Amendments) automatically applies the restricted indirect cost rate requirement to any DoEd grant program with a "supplement, not supplant" provision.

UTTC has no quarrel with the bases and objectives of the "supplement, not supplant" rule and seeks no change to this statutory provision. The primary targets of this rule are States and possibly local government entities that run vocational education programs with State or local funds.

By contrast, however, UTTC has little or no ability to violate this rule, as we have no source of non-federal funds to operate vocational education programs. Unlike States, we have no tax base and no source of non-federal funds to maintain a vocational education program. We depend on federal funding for our vocational/technical education program operations. Despite our inability to violate the supplanting prohibition, we are, nonetheless, being disadvantaged by a DoEd regulation intended to enforce the prohibition against States who do have the ability to supplant.

—*Impact of new requirement on grantees*.—Under DoEd regulations, a "restricted indirect cost rate" makes unallowable certain indirect costs that are considered allowable by other federal programs. Primarily, these are costs that DoEd believes the grantee would otherwise incur if it did not receive a Perkins grant, such as the cost of the grantee's chief officer and heads of departments who report to the CEO, as well as the costs of maintaining offices for these personnel.

Prohibiting the Perkins grant from contributing its appropriate share to the grantee's indirect cost pool will most likely mean that other federal programs operated by the grantee would be expected to pick up a great share of the indirect cost pool. This outcome may well result in objections from the other program agencies that do not want to bear costs properly attributable to the Perkins grant.

We are caught between conflicting federal agency requirements and will find ourselves unable to recover the necessary share of indirect costs attributable to each of the federal programs we operate.

United Tribes Technical College: Unique Inter-tribal Educational Organization.—Incorporated in 1969, United Tribes Technical College is the only inter-tribally controlled campus-based, postsecondary vocational institution for Indian people. We are chartered by the five tribes in North Dakota and operate under an Indian Self-Determination contract with the BIA. This year we enrolled 645 students from 44 tribes and 17 states. Our hope is to serve 2,000 adult students by the year 2008.

The majority of our students are from the Great Plains states that, according to the 1999 BIA Labor Force Report, has an Indian reservation jobless rate of 71 percent. UTTC is proud that we have an annual placement rate (placement in jobs or in higher education) of 90 percent. In addition, we serve 147 children in our preschool programs and 148 children in our Theodore Jamerson elementary school, bringing the population for whom we provide direct services to 940.

UTTC Course Offerings.—We offer 14 vocational/technical programs and award a total of 24 two-year degree and one-year certificates. We are accredited by the North Central Association of Colleges and Schools and we were re-accredited in 2001 for the longest time allowable—10 years or until 2011—and with no stipulations.

We are very excited about the recent additions to our course offerings, and the relevance they hold for Indian communities. These new programs are: Injury Prevention; On-Line Education; Nutrition and Food Services; Tribal Government Management, and Tourism.

Injury Prevention.—Through our Injury Prevention Program we are addressing the injury death rate among Indians, which is 2.8 times that of the total U.S. population. We received assistance through the IHS to establish the only degree granting Injury Prevention program in the nation. Injuries are the number one cause of mortality among Native people for ages 1–44 and the third for overall death rates. IHS spends more than $150 million annually for the treatment of non-fatal injuries, and treatment of injuries is the largest expenditure of IHS contract health funds (IHS fiscal year 2004 Budget Justification).

—*On-Line Education*.—We are bridging the "digital divide" by providing web-based education and Interactive Video Network courses from our North Dakota campus to American Indians residing at other remote sites, including the Denver Indian community, and plan to serve rural-based Indian tribes. Training is currently provided in the areas of Early Childhood Education and Computer Literacy. By the year 2005, students will be able to access full degree programs in Computer Technology, Injury Prevention, Health Information Technology, Early Childhood Education, and Office Technology, and others from these remote sites. UTTC is seeking accreditation to offer On-Line degree programs.

High demand exists for computer technicians. In the first year of implementation, the Computer Support Technician program is at maximum student capacity. In order to keep up with student demand, UTTC will need more classroom space, computers and associated equipment, and instructors. Our program includes all of the Microsoft Systems certifications that translate into high income earning potential for graduates.

—*Nutrition and Food Services*.—UTTC will meet the challenge of fighting diabetes in Indian Country through education. As you know, the rate of diabetes is very high in Indian country, with some tribal areas experiencing the highest incidence of diabetes in the world. About half of Indian adults have diabetes (Diabetes in American Indians and Alaska Natives, NIH Publication 99–4567, October, 1999).

We offer a Nutrition and Food Service Associate of Applied Science degree to increase the number of American Indians with expertise in human nutrition and dietetics. Currently, there are only a handful of Indian professionals in the country with training in these areas. Future improvement plans include offering a Nutrition and Food Service degree with a strong emphasis on diabetes education and traditional food preparation.

We have also established the United Tribes Diabetes Education Center to assist local Tribal communities and UTTC students and staff in decreasing the prevalence of diabetes by providing educational programs, materials, and training. UTTC has published and made available tribal food guides to our on-campus community and to tribes.

—*Tribal Government Management/Tourism*.—Another of our new programs is tribal government management designed to help tribal leaders be more effective administrators. We continue to refine our curricula for this program.

A newly established education program is tribal tourism management. UTTC has researched and developed core curricula for the tourism program with which we are partnering with three other tribal colleges (Sitting Bull, Fort Berthold, and Turtle Mountain). The development of the tribal tourism program was well timed to coincide with the national Lewis and Clark Bicentennial this year. As you may know, Lewis and Clark and their party spent one quarter of their journey in North Dakota. UTTC art students were commissioned by the Thomas Jefferson Foundation to create historically accurate reproductions of Lewis and Clark-era Indian objects using traditional methods and natural materials. Our students had partners in this project including the National Park Service and the Peabody Museum at Harvard University. The objects made by our students are now part of a major exhibition in the Great Hall at Monticello about the Lewis and Clark expedition.

Job Training and Economic Development.—UTTC is a designated Minority Business Center serving Montana and the Dakotas. We also administer a Workforce Investment Act program and an internship program with private employers.

Economic Development Administration funding has enabled UTTC to open a "University Center." The Center will help with tribal economic development. Most states have such centers. Ours is the first such tribal center.

Department of Education Study Documents our Facility/Housing Needs.—The 1998 Vocational Education and Applied Technology Act required the U.S. Department of Education to study the facilities, housing and training needs of our institution. That report, conducted for the Department by the American Institutes for Research, was published in November, 2000 ("Assessment of Training and Housing needs within Tribally Controlled Postsecondary Vocational Institutions, November 2000, American Institute of Research") The report identified the need for $16.6 million for the renovation of existing housing and instructional buildings ($8 million if some existing facilities are converted to student housing) and $30 million for the construction of housing and instructional facilities.

UTTC continues to identify housing as its greatest need. We have a huge waiting list of students some who wait from one to three years for admittance. New housing must be built to accommodate those on the waiting list as well as to increase enrollment. Enrollment for the 2002–2003 academic year has increased by 31 percent. In

order to accommodate the enrollment increase, UTTC partnered with local renters and the Burleigh County Housing Authority. Approximately 40 students and their dependents were housed off campus. Increased enrollment, while desirable, also presents challenges for transportation, cafeteria, maintenance and other services.

UTTC is building a new 86-bed single-student dormitory on campus. We formed a strategic alliance with the Departments of Education and Agriculture, the American Indian College Fund, the Shakopee Mdwekanton Sioux Tribe and other sources to build the dormitory. The new dorm will help us address our housing shortage. Existing housing must be renovated to meet local, state, and federal safety codes. In the very near future, some homes will have to be condemned which will mean lower enrollments and fewer opportunities for those seeking a quality education.

Classroom and office space are at a premium. We have literally run out of space. This means that we cannot expand its course offerings to keep up with job market demands. Most offices and classrooms that are being used are quite old and are not adequate for student learning and success. We were able to piece together three sources of funds (EDA, USDA, DOEd) to raise $1 million to renovate a building to create a new student life and technology center.

Thank you for your consideration of our request. We cannot survive without the basic vocational education funds that come through the Department of Education.

PREPARED STATEMENT OF THE AMERICAN INDIAN HIGHER EDUCATION CONSORTIUM

Mr. Chairman and Members of the Subcommittee, on behalf of this nation's 34 Tribal Colleges and Universities (TCUs), which comprise the American Indian Higher Education Consortium (AIHEC), thank you for the opportunity to share our fiscal year 2004 funding requests for programs within the Department of Education, and the Department of Health and Human Services—Head Start program.

This statement will cover two areas: (a) background on the tribal colleges, and (b) justifications for our funding requests.

BACKGROUND ON TRIBAL COLLEGES

The Tribal College Movement began in 1968 with the establishment of Navajo Community College, now Diné College, in Tsaile, Arizona. A succession of tribal colleges soon followed, primarily in the Northern Plains region. In 1972, the first six tribally controlled colleges established AIHEC to provide a support network for member institutions. Today, AIHEC represents 34 Tribal Colleges and Universities located in 12 states, begun specifically to serve the higher education needs of American Indian students. Collectively, these institutions serve 30,000 full- and part-time students from over 250 Federally recognized tribes.

The vast majority of TCUs are accredited by independent, regional accreditation agencies and like all institutions of higher education, must undergo stringent performance reviews on a periodic basis. In addition to college level programming, TCUs provide much needed high school completion (GED), basic remediation, job training, college preparatory courses, and adult education. Tribal colleges fulfill additional roles within their respective reservation communities functioning as community centers, libraries, tribal archives, career and business centers, economic development centers, public-meeting places, and child care centers. Each TCU is committed to improving the lives of students through higher education and to moving American Indians toward self-sufficiency.

Tribal colleges provide access to higher education for American Indians and others living in some of this nation's most rural and economically depressed areas. These institutions, chartered by their respective tribal governments, were established in response to the recognition by tribal leaders that local, culturally based education institutions are best suited to help American Indians succeed in higher education. TCUs combine traditional teachings with conventional postsecondary courses and curricula. They have developed innovative means to address the needs of tribal populations and are successful in overcoming long-standing barriers to higher education for American Indians. Since the first tribal college was established on the Navajo reservation, these vital institutions have come to represent the most significant development in the history of American Indian higher education, providing access to under-represented students and promoting achievement among students who may otherwise never have known postsecondary education success.

Despite their remarkable accomplishments, tribal colleges are the most poorly funded institutions of higher education in the country. Chronically inadequate funding remains the most significant barrier to their success. Funding for basic institutional operations of 24 reservation-based colleges is provided through Title I of the Tribally Controlled College or University Assistance Act (Public Law 95–471). Fund-

ing under the Act was first appropriated in 1981 and is still, over 20 years later, less than two-thirds of its authorized level of $6,000 per full-time Indian student. In fiscal year 2002,[1] these colleges received $3,916 per full-time equivalent Indian student. While mainstream institutions have a foundation of stable state tax support, TCUs must rely on annual appropriations from the Federal government for their basic institutional operating funds. Because TCUs are located on Federal trust territories, states have no obligation to fund them even for the non-Indian state-resident students who account for approximately 20 percent of TCU enrollments. Yet, if these same students attended any other public institution in the state, the state would provide basic operating funds to the institution.

Inadequate funding has left many of our colleges with no choice but to operate under severely distressed conditions. Many colleges are still housed in surplus trailers; cast-off buildings; and facilities with crumbling foundations, faulty wiring, and leaking roofs. Sustaining quality academic programs is a challenge without a reliable source of facilities maintenance and construction funding.

As a result of more than 200 years of Federal Indian policy—including policies of termination, assimilation and relocation—many reservation residents live in abject poverty comparable to that found in Third World nations. Through the efforts of tribal colleges, American Indian communities receive services they need to reestablish themselves as responsible, productive, and self-reliant.

JUSTIFICATIONS

Higher Education Act

The Higher Education Act Amendments of 1998 created a separate section within Title III, Part A, specifically for the nation's Tribal Colleges and Universities (Section 316). The Aid for Institutional Development programs, commonly known as the Title III programs, support institutions that enroll large proportions of financially disadvantaged students and have low per-student expenditures. TCUs clearly fit this definition as they are among the most poorly funded institutions in America, yet they serve some of the most impoverished areas of the country. The President's proposed increase for strengthening developing institutions programs under Higher Education Act was based on the fiscal year 2002 budget recommendations and not on the enacted fiscal year 2003 appropriations for these programs. The fiscal year 2003 Omnibus Appropriations bill includes $23 million for the tribal college Title III programs. Therefore, if enacted, the President's fiscal year 2004 Budget recommendation of $19 million would not result in an increase at all, but rather a $4 million decrease in these vital program funds. We strongly urge the Subcommittee fund section 316 at $27 million, an increase of $4 million over fiscal year 2003 and $8 million over the President's request, and we ask that report language included in fiscal year 2003 be restated to clarify that funds not needed to support continuation grants or new planning or implementation grants be available for facilities renovation and construction grants.

The importance of Pell grants to our students cannot be overstated. Department of Education figures show that at least half of all Tribal College students receive Pell grants, primarily because student income levels are so low and our students have far less access to other sources of aid than students at mainstream institutions. Within the Tribal College system, Pell grants are doing exactly what they were intended to do—they are serving the needs of the lowest income students by helping people gain access to higher education and become active, productive members of the workforce. We urge Congress fund this critical program at the highest possible level.

Carl D. Perkins Vocational & Applied Technology Education Act

Tribally-Controlled Postsecondary Vocational Institutions.—Section 117 of the Perkins Act provides basic operating funds for two of our member institutions: United Tribes Technical College in Bismarck, North Dakota, and Crownpoint Institute of Technology in Crownpoint, New Mexico. We urge Congress fund this program at $8 million and continue the language included in fiscal years 2002 and 2003 stating that Section 117 Perkins grantees need not utilize restricted indirect cost rate.

The President's fiscal year 2004 budget proposes the elimination of the Native American Program Section 116, which reserves 1.25 percent of appropriated funding to support Indian vocational programs. We strongly urge Congress continue this program, which is vital to the survival of vocational education programs being offered at TCUs.

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[1] As of this writing, the Bureau of Indian Affairs (BIA) has not released the per Indian Student Count (ISC) funding level for fiscal year 2003.

Greater Support of Indian Education Programs Under ESEA

American Indian Adult and Basic Education.—This section supports adult education programs for American Indians offered by TCUs, state and local education agencies, Indian tribes, institutions, and agencies. Despite a lack of funding, TCUs must find a way to continue to provide basic adult education classes for those Indians that the present K–12 Indian education system has failed. Before many individuals can even begin the course work needed to learn a productive skill, they first must earn a GED or, in some cases, learn to read. According to a 1995 survey conducted by the Carnegie Foundation for the Advancement of Teaching, 20 percent of the participating students had completed a tribal college GED program before beginning higher education classes at the tribal college. At some schools, the percentage is even higher. Clearly, the need for basic educational programs is tremendous, and TCUs need funding to support these crucial activities. Tribal colleges respectfully request that Congress appropriate $5 million to meet the ever-increasing demand for basic adult education services.

American Indian Teacher Corps.—American Indians are severely under-represented in the teaching and school administrator ranks nationally. These competitive programs, aimed at producing new American Indian teachers and school administrators for schools serving American Indian students, support the recruitment, training, and in-service professional development programs for Indians to become effective teachers and school administrators, and in doing so excellent role models for Indian children. We believe that the TCUs are the ideal catalysts for these initiatives because of our current work in this area and the existing articulation agreements TCUs hold with 4-year degree awarding institutions. We request Congress support these programs at $10 million and $5 million, respectively, to increase the number of qualified American Indian teachers and school administrators in Indian Country.

Department of Health and Human Services/Administration for Child, Youth and Families/Head Start

Tribal Colleges and Universities (TCU) Head Start Partnership Program.—The TCU/Head Start partnership has made a lasting investment in our Indian communities by creating and enhancing associate degree programs in Early Childhood Development and related fields. New graduates of these programs can help meet the mandate that 50 percent of all program teachers earn an associate degree in Early Childhood Development or a related discipline by 2003. One clear impediment to the on-going success of this partnership program is the decrease in discretionary funding being directed to the TCU/Head Start partnership. In fiscal year 1999, the first year of the program, six TCUs received awards; in fiscal year 2000, seven additional colleges received 3-year grant awards; in fiscal year 2001, new grants were extended to be 5-year grants but only $360,000 was made available for the program, allowing only three additional TCUs to receive grants; in fiscal year 2002 no additional grants were awarded. The extension of the duration for new grants was a welcome change. We are hopeful that the current (1999 and 2000 grantees) will be able to extend their existing grants to a total of 60 months. The President's budget includes a request of $6,815,570,000 for Head Start Programs. We request Congress direct the Head Start Bureau to designate a minimum of $5 million for the TCU/Head Start Partnership program, to allow current grantees to extend their programs for two additional years and to ensure that this critical program can be continued and be expanded so that all TCUs might offer Head Start partnership programs.

CONCLUSION

Tribal colleges are bringing education to thousands of American Indians. The modest Federal investment in the tribal colleges has paid great dividends in terms of employment, education, and economic development, and continuation of this investment makes sound moral and fiscal sense. We very much need help to sustain and grow our programs and achieve our missions.

Thank you again for this opportunity to present our funding requests. We respectfully ask the Members of this Subcommittee for their continued support of TCUs and full consideration of our fiscal year 2004 appropriations request.

PREPARED STATEMENT OF THE CROWNPOINT INSTITUTE OF TECHNOLOGY, CROWNPOINT, NM

This testimony addresses appropriations for Section 117 of the Carl D. Perkins Vocational Education Act, "Tribally Controlled Vocational and Technical Institutions."

On behalf of the Crownpoint Institute of Technology (CIT), I thank this Subcommittee for appropriating operational funds to Section 117 in the amount of $7 Million for fiscal year 2003. Because this appropriation is forward funded, CIT will not know its allocation under it until September 2003. From the fiscal year 2002 appropriation of $6.5 Million, CIT received $3,663,331. In addition, CIT extends it deepest gratitude to this Subcommittee for the accompanying appropriations language that addresses the Department of Education's use of restricted indirect cost rates to vocational grants under Section 117. The Subcommittee's language rectifies a serious problem wherein essential vocational education services were disallowed by the Department through the application of extraneous regulations. CIT endeavors to realize a long range solution to the problem of restricted indirect cost through the reauthorization of the law. The reauthorization is expected in 2003, but it may not occur until later. CIT urges this Subcommittee to continue the prohibition of restricted indirect cost by the Department if the authorizing statute is not reauthorized in 2003. CIT also strives to have other problems surrounding the Departmental allocation of appropriated funds corrected through the reauthorization.

CIT is the only postsecondary vocational educational institution on the Navajo Nation reservation. For academic year 2002–03, CIT's enrollment is 429 headcount: 517 Indian Student Count/Full Time Equivalency (ISC/FTE). CIT is open to all Indian and non-Indian applicants alike who meet admissions criteria, but the preponderance of applicants are of course Navajo Nation young adults who traditionally have not had access postsecondary vocational education due to geographic, cultural and economic isolation from mainstream postsecondary educational opportunities.

The Navajo reservation is an immense and remote 26,897 square miles extending into three States: Arizona, New Mexico and Utah. This reservation is 2,810 square miles larger than the State of West Virginia. The driving distance across the reservation is approximately nine hours. Although distant from major towns, Crownpoint is a major reservation activity center. CIT students come from throughout the reservation as well as from the towns of Gallup, Cruet, Continental Divide, Fruitland, Kirtland, Mentmore, Rehobeth (all in New Mexico), Durango, Colorado, White Mesa, Utah and the Tohono O'odham and Hopi Reservations in Arizona. Approximately 30 percent of CIT students are from the Arizona side of the Reservation.

The population of the Navajo Nation is 225,298 (U.S. Census 2000). The Navajo Nation is one of the very few tribes with an extant native language. Nearly all Navajo citizens raised on the reservation not only speak the Navajo language but also use it in their daily lives. On trust land alone, 106,432 Navajo citizens are age 18 and over. The decennial tribal population increase is 14 percent, as compared to only 8 percent for mainstream America. The median Native American population age is 27.4 years, eight years younger than the median age for mainstream America. Approximately 10,000 Navajo students graduate from area high schools each year. The average CIT student age is 26, with the actual age range being 18 to 64.

It is essential that appropriators understand the immense population difference that exists among Indian tribes. In contrast to Navajo, the sixteen tribes in the States of Montana, North Dakota and South Dakota have a combined population of 72,835. The Navajo Nation population is more than three-fold the population of these sixteen tribes. These sixteen tribes each have one tribal college available to their citizens on significantly smaller land bases. The Navajo Nation has only one other college, Dine', based in Tsaile, Arizona with eight small branch campuses throughout the reservation. Of the entire Navajo population, only 4.66 percent of high school graduates go on to achieve a bachelor's degree. Only 2 percent achieve Masters degrees, and less than one-half percent earn doctorates. CIT has proven to offer a realistic educational alternative that equips young adults with meaningful employment skills as well as placing graduates in career track employment.

In order to do so, CIT has broader infrastructure responsibilities. CIT is campus-based with 153,468 square feet of facilities. The CIT campus includes state of the art classrooms and Veterinary Clinic, modular administrative buildings, library, efficiency apartments, dormitory, married student housing and cafeteria. CIT has no recreation facility. CIT has a higher proportion of students who have developmental education needs, and longer distances to transport students. Despite many challenges, CIT earns achievements. In 2003, CIT received an excellence award from the U.S. Department of Agriculture for the second time for sincere commitment to student outcomes, one of only eight such awards nationally. Also in 2003, the CIT Culinary Arts Program students won the Hilton Hotels-sponsored creative culinary art award.

CIT continues to increase its student housing capacity with assistance from the Navajo Nation HUD. In 2003, another sixteen married and family student units were completed. Students with dependent families are among those most in need

of acquiring employment skills. CIT opened a new 75 unit efficiency housing for 150 students, but at the same time had to temporarily close its 110 unit dormitory for safety-related repairs to be completed in a year. Each year, CIT has averaged a waiting list of approximately 200 otherwise qualified students due to residential hosing limitations. Rental housing is scarce in the town of Crownpoint.

Daily commuting from most parts of the reservation is hindered by poor roads, harsh weather and vast distance, although some students do commute daily up to 70 miles each way. CIT has an eight-year average student retention rate of 95 percent, and an average job placement rate of 86 percent over that same period. Due to the Department's discretionary restrictions, CIT's student job placement office is understaffed. As a consequence, the job placement average has dropped to 75 percent. With additional resources, CIT could increase student job placement even further.

CIT is fully-accredited by North Central Association of Colleges and Schools as a vocational educational institution. CIT offers two-year Associate of Applied Science degrees in seven disciplines: Accounting, Administrative Assistant, Applied Computer Technology, Environmental Technology and Natural Resources, Law Advocate, Legal Assistant and Veterinary Technician. CIT offers sixteen vocational certificate programs: Accounting, Administrative Assistant, Applied Computer Technology, Automotive Technology, Building Maintenance, Carpentry, Culinary Arts, Electrical Trades, Environmental Technology and Natural Resources, Law Advocate, Legal Assistant, Nursing Assistant, Veterinary Assistant, Small Business Development (new), Commercial Drivers License and Computer Aided Drafting. In the upcoming year, CIT is ready to offer Alternative Energy to assist the many reservation areas that still do not have access to electricity and possibly never will.

In May 2002, CIT graduated 208 students. This reflects an increase of 25 percent in the number of graduates over the previous year, which was 167 graduates. Approximately 80 percent of CIT completions not continuing their educations had secured employment placement by the time they graduated. Of this number, 86 percent secured full-time employment with the remaining 14 percent accepting seasonal jobs. 54 percent secured employment on-reservation and 46 percent off-reservation. In addition, the region's economy is comprised significantly of self-employed ranchers who by definition are not placed in employment. Several CIT Veterinary students are self-employed ranchers who improve their livelihoods through knowledge and skills learned in the CIT Veterinary Program. Students continuing their educations are considered positive terminations.

Of the above graduating classes (375 students), the CIT Placement Office successfully tracked and job placed 82 percent (308). 92 CIT graduates (30 percent) continued their educations. Funding limitations inhibit the capability of the CIT Placement Office to track and place 100 percent, but indicators over time are that some graduates who do not maintain contact with the Placement Office after graduation may do so because they have no need for job placement services. In other words, they find employment on their own. Of those graduates utilizing CIT placement services the following were placed in jobs or continued their education: Accounting 10 of 10 (100 percent): Administrative Assistant 30 of 43 (70 percent): Applied Computer technology 24 of 44 (55 percent): Automotive Technology 19 of 20 (95 percent): Building Maintenance 15 of 18 (83 percent): Carpentry 17 of 20 (85 percent): Culinary Arts 9 of 12 (75 percent): Electrical Trades 20 of 22 (91 percent): Environmental Technology and Natural Resources 17 of 23 (74 percent): Legal Assistant 5 of 5 (100 percent): Law Advocate 5 of 8 (63 percent): Nursing Assistant 34 of 52 (65 percent): Veterinary Assistant 10 of 13 (77 percent): Commercial Drivers License 16 of 18 (89 percent). Other variables affect employment success rates. For example, Nursing Assistants are in high demand. However, due to housing scarcity and transportation obstacles, several CIT Nursing Assistant graduates were unable to accept jobs offered.

Of all CIT graduates, the average entry level wage is $17,160 per annum. CIT's Commercial Drivers License (CDL) program graduates earn the highest wage at $16 to $18 an hour, or $33,280 to $37,440 annually if employment remains stable. The next highest paid entry-level wages average by vocational program are: Veterinary Technician/Assistant $23,920: Legal Advocate/Assistant $21,320: Electrical Trades $20,280: Automotive and Environmental Technology, both at $19,760. Even the modest entry-level wages can be deceiving as to the wage once established in that profession. For example, an electrical apprentice will start at $9/$11 hourly. This wage will more than double to $22/$28 hourly in 3½ to 4 years.

For Associate degree students continuing their educations, CIT has articulation agreements with University of New Mexico Albuquerque and Gallup, New Mexico State, Ft. Lewis College, University of Arizona and Northern Arizona University. The University of Pennsylvania and Iowa State University interns participate in

CIT's Elk Management Program. In addition, CIT partners this program with the Tohono O'odham Tribe of Arizona where livestock is critical to subsistence. In the Tohono O'odham partnership, CIT addresses the very real problem of migratory livestock disease transmission from across the Mexico border.

Partnering with Iowa State and Colorado State Universities, CIT offers an elk and cattle artificial insemination program for the region's ranchers. In response to overgrazing, the Elk Management Program has proven to be a viable alternative livestock offering a three-fold return over traditional livestock.

Less than four year ago, CIT did not yet have its own internet access. With the generous assistance of Section 117 appropriations from this Subcommittee, CIT is achieving state of the art technology with a now fully-operational Distance Learning capability. Partnering with Northern Arizona University and Window Rock Unified School District, CIT's vocational offerings will now expand to high school students in Two plus Two Programs in the farthest reaches of the reservation. Also, NAU programs can now be brought to CIT students, and CIT faculty can partake of professional development without the time and expense of leaving the campus. In the extreme geographic isolation of the reservation, distance learning capability holds the promise of enabling even more educational opportunities on a par with those more readily available in urban and suburban America. In order for CIT graduates to be competitive for America's jobs, they must be able to acquire equal employability skills.

In an average lifetime of employment, CIT graduates will return to the Federal Government the cost of its investment many times over. Each employed graduate pays an average of $2,576 of their earnings to federal taxes in the first year of employment alone. Actual taxes paid differ according to a number of variables, but wage earnings and resultant tax contributions will generally continue over at least thirty years. CIT lacks institutional resources to track all of its graduates over the past two decades, but of those tracked 62 percent are employed in private industry and do not rely directly or indirectly on federal appropriations for jobs.

While CIT's CDL program graduates can earn high wages, it is an extremely limited offering. An actual tractor-trailer must be utilized and class size limit is four students per session. Strict State licensing standards require a paved training lot of over 300 feet in either direction. Until now, CIT offered the CDL course on it overflow campus parking lot. However, the Navajo Nation's new Empowerment Building for Temporary Assistance to Needy Families (TANF) on the CIT campus will now utilize this space. The Empowerment Center fills a previously unmet need and will house CIT's Adult Basic Education Classroom for its 172 students, serve 500 Eastern Navajo area families and employ 32 staff. This will fill the overflow parking lot to capacity. Importantly, this same parking lot also served as the training ground for Defensive Driving training for 102 Head Start bus drivers from throughout the area. Now, neither the CDL nor the Head Start bus driver training courses will have a training lot. Unless funding is found for a replacement training lot, this highly successful CDL program will have to be discontinued.

As is prevalent throughout the economically disadvantaged in Native America, many high school graduates are not equipped with skills necessary to enter postsecondary education. To rectify this deficiency among some CIT applicants, CIT will hold its first summer session of Developmental Studies in 2003. This session will run for five weeks for approximately 150 entering students. Participating students will have the opportunity to achieve readiness skills by the start of the fall semester. To maximize the benefit to the community, CIT plans to simultaneously conduct five one week Computer and Math Camps for K–12.

CIT continually strives to strengthen its programs. In 2003 CIT will enhance articulation agreements with San Juan and Dine Colleges through standardization of course offerings, particularly in the math and sciences. Through such measures CIT can more effectively ascertain student achievement and modify course offerings as necessary. This will increase access to continued education at four-year institutions for CIT graduates with the goal to further their educations. CIT will require additional resources to retain adjunct faculty in order to achieve this goal.

On behalf of all the CIT students whose quality of life has been immensely improved by Section 117 appropriations; I thank this Subcommittee for all of its assistance. CIT still faces the challenges described above, and will deeply appreciate and maximally benefit from any increases possible from this Subcommittee.

RELATED AGENCIES

PREPARED STATEMENT OF THE NATIONAL MINORITY PUBLIC BROADCASTING CONSORTIA

—National Asian American Telecommunications Association
—National Black Programming Consortium
—Latino Public Broadcasting Project
—Native American Public Telecommunications
—Pacific Islanders in Communications

The National Minority Public Broadcasting Consortia (Minority Consortia) submits this statement on the fiscal year 2006 appropriation for the Corporation for Public Broadcasting (CPB). Our primary missions are to bring a significant amount of programming from our communities into the mainstream of PBS and public broadcasting. In summary, we ask the Committee to:

—Reject the Administration's proposal to end advance funding of the Corporation for Public Broadcasting
—Reject the Administration's proposal to divert $100 million of already appropriated fiscal year 2004 funds to digital conversion and satellite interconnection
—Recommend at least $410 million for CPB for fiscal year 2006, a $20 million increase over fiscal year 2005
—Encourage CPB to increase its efforts for diverse programming with commensurate increases for minority programming and the Minority Consortia
—Support CPB's request of $60 million for digital conversion, but require that some of it be made available to independent producers, not only to stations

We are taken aback at the Administration's proposals regarding public broadcasting, and can only conclude that they are out of touch with the American public and with Congress when it comes to appreciating the education, services, and entertainment brought to us by public broadcasting. The quality gap between network television and public television has never been wider, and it continues to grow with each new "reality" show. Administration proposals to end forward funding of CPB, and to rescind funds, and to divert already appropriated funds would dramatically reduce the development of programming for public broadcasting.

Advance Funding.—We strongly oppose the Administration's proposal that the advance funding for CPB be eliminated, a proposal that would stop CPB funding for two years. We appreciate that Congress has rejected this proposal each of the last two years and that the fiscal year 2004 budget resolution assumes that CPB will remain advance funded. Reasons to continue advance funding for CPB include:

—The production of programming for public broadcasting usually takes several years and substantial lead time is needed for planning.
—Public broadcasting programs are supported by multiple funding sources, and two years advance knowledge of the amount of federal funding allows CPB to better leverage its federal funds to bring in other sources of revenue.
—The Minority Consortia administers a significant amount of CPB programming monies, and elimination of advance funding would negatively affect our organizations' planning and fundraising activities.
—Proposed Diversion of fiscal year 2004 CPB Funds.

We are extremely concerned about the Administration's proposal to divert $100 million of already appropriated fiscal year 2004 CPB funds ($380 million) to digital conversion ($80 million) and satellite interconnection ($20 million). Such a diversion of funds would wreck havoc on our organizations and the independent producers that we help support as well as many radio and television stations. We would be faced with a 25 percent reduction of CPB funds should Congress approve this proposal by the Administration.

CPB fiscal year 2006 Appropriation.—We support a fiscal year 2006 federal appropriation for CPB of at least $410 million. This would be a reasonable, albeit modest, contribution toward our national treasure of public broadcasting. The debate of the past several years regarding public television and public radio has highlighted the great esteem in which they are held.

Public broadcasting, including PBS and NPR, is particularly important for our nation's growing minority and ethnic communities. While there is a niche in the commercial broadcast and cable world for quality programming about our communities and our concerns, it is in the public broadcasting industry where minority communities and producers are more able to bring quality programming for national audiences. Additionally, public television and radio is universally available.

Digital Conversion Assistance.—We support CPB's request for $60 million for digital conversion funding for CPB.

With stations able to broadcast on multiple channels, there will be a need for a tremendous amount of new, quality public broadcasting programming. There are costs involved in the conversion which go beyond the significant equipment and hardware needs of stations. It will also take additional money to produce programming for digital broadcast. All producers face these new, higher costs.

Part of the equation in bringing more high quality diverse programming to public broadcasting is that independent producers be able to transition to digital production. Federal funding for digital conversion should include assistance for independent producers.

The Minority Consortia works closely with CPB. We value our relationship with President Coonrod and the CPB staff and appreciate the financial and technical assistance provided to us by that organization. We do not doubt CPB's commitment to increasing the diversity of programming on public television and radio but also believe they can do more with the resources at hand. The oft-stated commitment of CPB and Congress for increased multicultural programming combined with six years of funding increases should translate into significant progress. We urge this Committee to communicate with CPB about its efforts to bring more quality multicultural programming to public television.

Thank you for your consideration of our recommendations. We see new opportunities to increase diversity in programming, production, audience, and employment in the new media environment, and thank you for your long time support of our work on behalf of our communities.

PREPARED STATEMENT OF THE NATIONAL FEDERATION OF COMMUNITY BROADCASTERS

Thank you for the opportunity to submit testimony to this Subcommittee regarding the appropriation for the Corporation for Public Broadcasting (CPB). As the President and CEO of the National Federation of Community Broadcasters, I speak on behalf of over 200 community radio stations and related organizations across the country. This includes the new Low Power FM service that has just been authorized by the FCC. NFCB is the sole national organization representing this group of stations, which provide service in both the smallest communities and largest metropolitan areas of this country. Nearly half of our members are rural stations, and half are minority controlled stations.

In summary, the points we wish to make to this Subcommittee are that NFCB:

—Requests $410 million CPB for fiscal year 2006, a $20 million increase over fiscal year 2005 advance appropriation;

—Requests $60 million in fiscal year 2004 for conversion of public radio and television to digital broadcasting. Also requests $20 million for the Public TV interconnection system;

—Requests that advance funding for CPB is maintained in order to preserve journalistic integrity and facilitate planning and local fundraising by public broadcasters;

—Requests report language to ensure that CPB utilizes digital funds it receives for radio as well as television needs;

—Supports CPB activities in facilitating programming services to Latino and Native American radio stations;

—Supports CPB's efforts to help public radio stations utilize new distribution technologies, and requests that the Subcommittee ensure these technologies are available to all public radio services, not just those with the greatest resources.

Community radio fully supports $410 million for the Corporation for Public Broadcasting in fiscal year 2006.—Federal support distributed through the CPB is an essential resource for rural stations and for stations serving minority communities. These stations provide critical, life-saving information to their listeners. Yet they are often in communities with very small populations and limited economic bases, so that the ability of the community to financially support the station is insufficient without federal funds.

In larger towns and cities, sustaining grants from CPB enable community radio stations to provide a reliable source of noncommercial programming about the communities themselves. Local programming is an increasingly rare commodity in a nation dominated by national program services and concentrated ownership of the media.

For the past 28 years, CPB appropriations have been enacted two years in advance. This insulation has allowed pubic broadcasting to grow into a respected, independent, national resource that leverages its federal support with significant local funds. Knowing what funding will be available in advance has allowed local stations to plan for programming and community service, and to explore additional non-gov-

ernmental support to augment federal funds. Most importantly, the insulation that forward-funding provides "go[es] a long way toward eliminating both the risk of and the appearance of undue interference with and control of public broadcasting." House Report 94–245.

For the last few years, CPB has increased support to rural stations and committed resources to help public radio take advantage of new technologies such as the internet and satellite radio. We commend these activities, which we feel provide better service to the American people, but want to be sure that smaller stations with more limited resources are not left out of this technological transition. We ask that the Subcommittee include language in the appropriation that will ensure funds are available to help the entire public radio system utilize the new technologies, particularly rural and minority stations.

NFCB commends CPB for the leadership it has shown in supporting and fostering programming services to Latino stations and Native American stations. Satélite Radio Bilingüe provides 24 hours of programming to stations across the United States and Puerto Rico, addressing issues of particular interest to the Latino population. In the same way, American Indian Radio on Satellite (AIROS) distributes programming for Native American stations, arguably the fastest growing group of stations. There are now over 30 stations controlled by and serving Native Americans, primarily on Indian reservations.

Almost two years ago, CPB funded an historic Summit of Native American Radio in Warm Springs, Oregon. It was an extremely important opportunity for Native American stations and producers to strategize (with each other, and with colleagues from Public Radio and Native America) on ways to improve radio service to all Native Americans. CPB funded a similar Summit for Latino Public Radio, which took place this past September in Rohnert Park, California, home of the first Latino Public Radio station. These Summits have expanded the circle of support for Native and Latino Public Radio, and identified projects that will both improve efficiency among stations through collaborations, and explore new ways of reaching target audiences.

CPB plays a very important role in the public and community radio system. They are the convener of discussions on critical issues facing us as a system. They support research so that we have a better understanding of how we are serving listeners. And they provide funding for programming, new ventures, expansion to new listeners, and projects that improve the efficiency of the system. This is particularly important at a time when there are so many changes in the radio and media environment, with new distribution technologies and media consolidation. An example of this support is the grant that NFCB received to update and put our Public Radio Legal Handbook online. This provides easy to read information to stations about complying with governmental regulations, so that stations can function legally and use their precious resources for programming instead of legal fees.

Finally, community radio supports $60 million in fiscal year 2004 for conversion to digital broadcasting by public radio and television.—It is critical that this digital funding be in addition to the on-going operational support that CPB provides. The Administration's proposal that digital money should be taken from the fiscal year 2004 CPB appropriation would effectively cut stations' grants by more than 25 percent. This would have a devastating impact during these hard economic times, when stations are facing cuts from state and institutional funds at historic levels. And it would come at a time when the local voices of community and public radio are especially important, both to notify and support people during emergency situations and to help communities deal with the loss of loved ones—things that commercial radio is no longer able to do because of media consolidation.

While public television's digital conversion needs are more immediate, the Federal Communications Commission has now approved a standard for digital radio transmission. We expect that there will be funds available for radio conversion as well as television conversion. The initial conversion of radio stations is being concentrated in 13 seed markets. CPB is using some of the previously appropriated digital funds to help public stations in these markets convert to digital, conduct additional research on AM radio conversion, and work with radio receiver manufacturers to build in the capacity to receive a 2nd audio channel. The development of 2nd audio channels will potentially double the public service that public radio can provide, particularly to unserved and underserved communities. This initial funding will only help a small number of the stations that will ultimately need to convert or be left behind while the world goes digital.

Community Radio also supports $20 million in fiscal year 2004 for the public television interconnection system.

Federal funds distributed by CPB should be available to all public radio stations eligible for Federal equipment support through the Public Telecommunications Facilities Program (PTFP) of the National Telecommunications and Information Agen-

cy of the Department of Commerce. The PTFP criteria for funding are exacting, but allow for wider participation among public stations. Stations eligible for PTFP funding and not for CPB funding include small-budget, rural and minority controlled stations.

We appreciate Congress' direction to CPB that it utilize its digital conversion fund for both radio and television, and ask that you ensure that the funds are used for both media. Congress stated, with regard to fiscal year 2000 digital conversion funds:

"The required (digital) conversion will impose enormous costs on both individual stations and the public broadcasting system as a whole. Because television and radio infrastructures are closely linked, the conversion of television to digital will create immediate costs not only for television, but also for public radio stations (emphasis added). Therefore, the Committee has included $15,000,000 to assist radio stations and television stations in the conversion to digitalization. . . ." (S. Rpt. 105–300)

This is a period of tremendous change. Digital is transforming the way we do things; new distribution avenues like digital satellite broadcasting and the Internet are changing how we define our business; concentration of ownership in commercial radio makes public radio in general and community radio in particular more unique, and more important as a local voice than we have ever been. Low Power FM stations are providing new local voices in their communities. Community radio is providing essential local emergency information, programming about the local impact of major global events, culturally appropriate information and entertainment in the language of the native culture, and help in preserving cultures that are dying out.

During this time, the role of CPB as a convener of the system becomes even more important. The funding that it provides will allow smaller stations to participate along with larger stations which have more resources, as we move into a new era of communications.

Thank you for your consideration of our testimony. If the Subcommittee has any questions, or needs to follow-up on any of the points expressed above, please contact: Carol Pierson, President and CEO, National Federation of Community Broadcasters, 1970 Broadway, Suite 1000, Oakland, CA 94612—Telephone: 510 451–8200—Fax: 510–451–8208—E-mail: carol@nfcb.org

The NFCB is a twenty-eight year old grassroots organization which was established by and continues to be supported by our member stations. Large and small, rural and urban, NFCB member stations are distinguished by their commitment to local programming, community participation and support. NFCB's 100 Participant members and 100 Associates come from across the United States, from Alaska to Florida; from every major market to the smallest Native American reservation. While urban member stations provide alternative programming to communities that include New York, Minneapolis, San Francisco and other major markets, rural members are often the sole source of local and national daily news and information in their communities. NFCB's membership reflects the true diversity of the American population: 41 percent of members serve rural communities, and 46 percent are minority radio services.

On community radio stations' airwaves examples of localism abound: on KWSO in Warm Springs, Oregon, you will hear morning drive programs in their Native language; throughout the California farming areas around Fresno, Radio Bilingüe programs five stations targeting low-income farm workers; in Barrow, Alaska, on KBRW you will hear the local news and fishing reports in English and Yupik Eskimo; in Dunmore, West Virginia, you will hear coverage of the local school board and county commission meetings; KABR in Alamo, New Mexico serves its small isolated Native American population with programming almost exclusively in Navajo; and on WWOZ you can hear the sounds and culture of New Orleans throughout the day and night.

In 1949 the first community radio station went on the air. From that day forward, community radio stations have been reliant on their local community for support through listener contributions. Today, many stations are partially funded through the Corporation for Public Broadcasting grant programs. CPB funds represent under 10 percent of the larger stations' budgets, but can represent up to 50 percent of the budget of the smallest rural stations.

Prepared Statement of the Medicare Payment Advisory Commission

The Medicare Payment Advisory Commission (MedPAC) requests a budget appropriation of $9.3 million for fiscal year 2004. This request for a $1.1 million increase

over the Commission's fiscal year 2003 appropriations reflects the increasing need for better understanding of the policy issues for one of the Congress' highest priorities—and with more than 40 million beneficiaries costing $250 billion per year—one of the federal governments largest programs. This budget also funds increases resulting from higher rent, benefit costs, and new MedPAC products and services.

Legislative mandate.—MedPAC is authorized under section 1805 of the Social Security Act (42 U.S.C. 1395 b–6), as added by section 4022 of the Balanced Budget Act of 1997 (Public Law 105–33). The Commission consists of 17 Commissioners, appointed by the Comptroller General of the General Accounting Office, who possess expertise in biomedical, health services, and health economics research and who draw on their experiences as consumers, providers, employers, and payers. An executive director, analytic and administrative/operational personnel staff the Commission. To produce the March, June, and other reports mandated by legislation, the Commission meets publicly throughout the year.

MedPAC is a small efficient operation.—The Commission works under a staffing ceiling of 40 FTEs and outsources 40 percent of its budget for tasks such as data analysis, programming, printing, editorial work, and selected research projects to maintain efficiencies. Each year, our annual appropriations provide the resources necessary to complete the Commission's required activities, including:

—*March Report to the Congress*.—This report always includes recommendations on the appropriate levels of payment for Medicare providers and policies to address the distribution of payments within a segment of the market (for example, our March 2003 recommendations to improve payments for certain providers in rural areas).

—*June Report to the Congress*.—Previous reports have addressed issues such as Medicare in rural America, payments for new technologies, and a variety of other topics. The June 2003 report will address a broad range of policy concerns about variations in the Medicare program and innovations in purchasing.

—*Reports required by other legislation*.—During fiscal years 2002 and 2003, MedPAC issued 15 separate reports to Congress on a variety of issues as required by the Balanced Budget Refinement Act and the Benefits Improvement and Protection Act.

—*Comments on administrative actions*.—MedPAC is required to comment on payment-related reports that the Secretary submits to the Congress and other proposed rules issued by the Centers for Medicare and Medicaid Services. These include comments on CMS's estimate of the update for physician services, evaluation of demonstration projects like the Medicare social health maintenance organizations, and reviews of new payment systems being phased in for certain types of providers.

MedPAC is expanding its services to meet growing demands for Medicare policy analysis.—Part of the additional funds we request also will support other analysis and education provided by the Commission. On top of our statutorily required work, the Commission staff serve as critical resources to the Senate Finance, House Ways and Means, and House Energy and Commerce committees in a variety of ways. Meeting the growing number and scope of requests for information and analysis from congressional staff requires increases in staff time and other resources. While some of these new initiatives will require additional funding, we expect that distributing many of our future work products electronically will save federal dollars.

In the 2003 fiscal year, we have stepped up the amount of assistance provided to congressional staff at the urging of our authorizing committees, and by extension, stretched our human and financial resources to projects not specifically mandated in legislation. Some of these new activities include:

—*Congressional briefings*.—For example, MedPAC coordinated a series of weekly briefings for Finance committee staff on the intricacies of the payment systems. These 90-minute briefings detail how the payment systems work and what the major policy concerns are in each sector of the Medicare program. We also worked with other legislative branch agencies to provide a 2-day briefing for all personal member and committee health legislative staff on Medicare, Medicaid, and SCHIP issues.

—*Informational memos*.—At the request of committee staff or through our own initiation, we've begun to issue briefing papers to our authorizing committees' staff on timely issues that synthesize the facts and present policy considerations. Previous memos explained Medicare's outlier payment policy for hospital services and the bankruptcy of National Century Financial Enterprises (a financier of many health care providers). Future memos will explain topics such as how Medicare pays for physician's professional liability premiums and geographic variation in Medicare spending.

—*New tools and other publications*.—The staff fulfill many requests from congressional offices for data on providers' financial performance, trends in utilization, and beneficiary characteristics. In June 2003, MedPAC will release a data book compiling useful facts and figures to serve as a quick reference for personal member and committee staff. Over time, the collection of charts in the data book will be complemented by an expanded web-based data collection on our website.

MedPAC is expanding the scope of its analyses to include emerging and dynamic policy issues affecting beneficiaries, providers, and spending.—Historically, the Commission provided the Congress with a wealth of information about existing payment systems as well as guidance on the design and implementation of new programs. Since the Balanced Budget Act, we have recommended annual payment updates for Medicare providers and provided input and recommendations on Medicare + Choice, new payment systems for home health, skilled nursing facilities, psychiatric hospitals, long-term care hospitals, and many other providers. Beginning with our March 2003 report, we are highlighting the implications of these recommendations on three important issues: spending, beneficiaries, and providers.

Along with the increased urgency over Medicare reform and possible coverage of prescription drugs, there has been a comparable increase in the information requests submitted to us from the Congress. Commission staff have further responded, both orally and in writing, to numerous requests from Congressional staff on a wide variety of topics. Not including minor requests, Commission staff have filled over 75 direct requests for information from Congressional staff, involving meetings, briefings, data, and other substantive analyses.

In completing our mandated reports and providing analytic support to the Congress, Commission staff have reached out to the public, interested parties, and the research community for input and to further public understanding of the Commission's work. Commission staff made over 50 public presentations to Commissioners as well as presenting to local, national, and even international audiences. Staff have held more than 30 meetings with interest groups and regulated parties on a variety of topics. Finally, staff have worked with health services researchers and the health policy community to further the Commission's work and encourage sharing of information that could extend our research and analytic efforts.

Looking ahead, the Commission sees a growing need for analysis and education on many emerging and dynamic issues. We are already receiving requests from Congressional staff to provide them with guidance on a broad range of issues-some of which will be addressed in our plans for future analytic work outlined below:

—Outpatient drugs
—Coverage and payment for new technology
—Post-acute episodes of care
—Dually eligible beneficiaries
—Disease management
—Growth in the volume of physician services
—The financial performance of hospitals and other Medicare providers
—Incentives for quality in traditional Medicare
—Competition in fee-for-service Medicare
—Understanding health insurance markets and choices for beneficiaries
—Indirect medical education (IME)
—Geographic variation in Medicare payments

MedPAC needs new resources to expand our analytic capacity.—With each analytic year that passes, the inadequacy of the data available to assess the Medicare program becomes more evident. To successfully fulfill our role as adviser to the Congress, we must expand data sources and the depth of our analysis to better understand provider and beneficiary needs. Again, such endeavors will require increased funding. The additional resources requested in our 2004 appropriations will allow MedPAC to accomplish its congressionally mandated mission and meet these emerging analytic needs by:

—*Expanding the scope of our analysis*.—The growing clinical importance and cost of new technology, outpatient drugs, and many other services for Medicare beneficiaries is clear. To fully investigate and educate the Commission and congressional staff about complex policy issues in a rapidly changing environment requires an expansion of our current staff capacity and capabilities. This expansion will improve ongoing commission work and enable us to meet the increasing number of inquiries from our authorizing committees for research and analysis in a timely manner.

—*Maintaining and increasing our recruitment and retention of highly skilled staff*.—MedPAC's ability to advise the Congress on the $250 billion Medicare program hinges on our ability to recruit and retain a talented staff who bring

years of experience and analytic rigor to bear on the important questions we address. The skills our staff possess are sought by research firms, other government agencies, and top consulting firms. To compete in this market for skilled staff, particularly against the private sector, we must be able to provide competitive salaries and benefits.

—*Enhancing our ability to supplement staff work with contracted research*.—While working under a staffing cap of 40 FTEs, the Commission regularly outsources important analyses that inform Commission recommendations. Research funds will be used to conduct surveys and analyses by outside contractors, acquire private sector data such as cost and revenue information from hospitals to update existing files, and take advantage of new resources. Given the rapid pace of changes in the Medicare program, it also is critical to continue to monitor beneficiaries' access to Medicare providers as well as other research projects on issues such as the use of outpatient prescription medications, the characteristics of health insurance markets, patterns of use of post-acute care services.

—*Increasing the Commission's ability to respond to requests for technical assistance*.—The volume of requests has grown this year, and we expect that trend to continue. While fulfilling these requests is a vital part of our service to the Congress, this additional workload strains our ability to complete work on statutorily required activities.

—*Providing resources to meet the day-to-day needs of congressional staff*.—We plan to improve our website so resources such as background information, additional data, and detailed policy explanations that complement our reports can be easily accessed. While we anticipate saving money on printing and postage through this shift, we will incur additional information technology costs to create this new platform.

Unavoidable new expenses are consuming a larger part of the Commission's annual appropriations.—In August 2002, the Commission was forced to relocate to new office space as a result of a planned demolition of its previous office location. The rent negotiated for us at our new location by the General Services Administration (GSA) resulted in substantial increase over prior years and added new overhead expenses, such as security. In addition, the growth in the cost of employee health insurance has added a tremendous burden to our personnel budget.

MedPAC's work informed congressional and executive branch decisions during fiscal years 2002 and 2003.—During fiscal years 2002 and 2003, the Commission submitted its annually mandated March and June reports, as well as a range of reports mandated under the BBRA and BIPA. The March 2002 and March 2003 reports focused on specific issues relating to payment policies and presented recommendations to the Congress on updating payments to providers of services to Medicare beneficiaries. Again, in a program that spends $250 billion dollars, these payment update recommendations have immense repercussions for the federal budget.

The June 2002 report focused on the Medicare benefit package, presenting the Congress with an assessment of the need for changes, a description of the coverage available to supplement the basic benefit package, and options for changing Medicare benefits. This report provided the Congress with a crucial perspective on assessing the Medicare benefit package, gaps in coverage of the current benefits package, and approaches to consider in revising that package.

The June 2003 report will address conceptual issues facing the Congress relating to mechanisms for moving the program forward in the areas of quality, access, program efficiency, and new payment system design. Some of the topics addressed in the report include experience with market competition in fee-for-services Medicare; alternatives to average wholesale price as a mechanism for paying for pharmaceuticals; and use of quality incentives in Medicare. It will also include our annual mandated review of the Secretary's estimate of the update for physician services. We further anticipate production and submission of a Medicare data book in June 2003, as requested by health committee staff. By 2004, we plan to supplement the annual data book with a web-based resource that can be updated to meet future requests for information.

Reports mandated by previous legislation have been completed on schedule, and include:

—Adjusting payments for local differences in resident training costs
—Quality improvement standards in fee-for-service Medicare and Medicare+Choice plans
—Medicare coverage of cardiac and pulmonary rehabilitation services
—State level variation in Medicare spending
—Medicare beneficiaries' access to and use of hospice
—Medicare payment to advanced practice nurses and physician assistants
—Medicare coverage of nonphysician practitioners

—Choice of skilled nursing facility services in Medicare + Choice
—Analysis of CMS' report on PPS for inpatient psychiatric facilities

MedPAC also commented on proposed rules for long-term care hospitals, hospital outpatient services, revisions to the physician fee schedule, and the hospital inpatient prospective payment system. In addition, the Commission Chairman has testified three times before the Subcommittee on Health, House Committee on Ways and Means during fiscal year 2002 and 2003 on physician payment policy, adjusting Medicare payments for local market input prices, and the Commission's payment recommendations for fiscal year 2004. The Commission expects to provide further testimony during the remainder of fiscal year 2003 and fiscal year 2004.

Congress and the executive branch have used MedPAC products and services.—MedPAC has provided both direct and indirect support to the policy process in the Congress and the executive branch. The Congress and the Centers for Medicare and Medicaid Services have adopted MedPAC's recommendations on a number of issues, including on risk adjustment, rural home health agencies and the prospective payment system, and on productivity adjustments for physician services. In addition, MedPAC deliberations and reports have influenced the debate in the Congress. As described above, members and staff have sought MedPAC's analytic support to help them better assess the issues.

Commission administration and management.—The Commission believes that its request for an appropriation of $9.3 million is necessary not only to maintain but also to increase the current level of analysis, data development, and operations required to fulfill and exceed our mandated responsibilities to the Congress. This additional funding will also cover an increase in rental and security costs from forced office relocation, as well as increased costs for employee health insurance. Under contract to MedPAC, the General Services Administration (GSA) provides payroll and accounting services, arranges for office space, telecommunication services, and travel services at government contract rates. The Commission obtains computer services from the National Institutes of Health, but is attempting to move to an alternative computing platform to minimize costs.

Issues relating to the Medicare program remain at the forefront of Congressional deliberations. MedPAC requires a budget of $9.3 million to adequately support the Congress in its deliberations on these issues.

PREPARED STATEMENT OF THE RAILROAD RETIREMENT BOARD

Mr. Chairman and Members of the Committee: We are pleased to present the following information to support the Railroad Retirement Board's (RRB) fiscal year 2004 budget request.

The RRB administers comprehensive retirement/survivor and unemployment/sickness insurance benefit programs for railroad workers and their families under the Railroad Retirement and Railroad Unemployment Insurance Acts. The RRB also has administrative responsibilities under the Social Security Act for certain benefit payments and Medicare coverage for railroad workers. During fiscal year 2002, the RRB paid $8.6 billion in retirement/survivor benefits to more than 684,000 beneficiaries, and $128 million in unemployment/sickness insurance benefits to over 39,000 claimants.

PRESIDENT'S PROPOSED FISCAL YEAR 2004 BUDGET

The President's proposed budget includes $99.82 million for RRB administrative expenses in fiscal year 2004. This total includes $97.72 million for the ongoing costs of current agency operations, which is the same as the amount included in the President's proposed budget for fiscal year 2003, but $2.28 million less than our initial appropriation of $100 million, before the 0.65 percent rescission under the Consolidated Appropriations Act, 2003 (Public Law 108–7). In addition, the President's proposed budget includes $2.1 million to contract with a non-governmental disbursement agent for payment of railroad retirement and survivor benefits in accordance with provisions of the Railroad Retirement and Survivors' Improvement Act of 2001 (Public Law 107–90).

Our Justification of Budget Estimates, released on February 12, 2003, indicated that the proposed funding would be sufficient for a staffing level of 1,019 full-time equivalent staff years (FTE's). The estimate reflected guidance from the Office of Management and Budget, which assumed pay increases of 3.1 percent in January 2003 and 2.0 percent in January 2004. The projection was subsequently updated to reflect the January 2003 pay increase of 4.1 percent enacted under Public Law 108–7. We now estimate that the President's proposed level of funding will be sufficient for about 1,008 FTE's, which is 73 fewer FTE's than the RRB plans to use in fiscal

year 2003. This represents a cumulative reduction of 41 percent in our agency's staffing since fiscal year 1993.

In order to operate at the President's proposed budget level in fiscal year 2004, we would need to make extremely deep cuts in funding for administrative costs throughout the RRB. We would first attempt to minimize any disruption in customer service by reducing costs which are indirectly related to these activities. In fiscal year 2003, we have already suspended most of our employee benefit programs, including transit benefit subsidies, medical exams, and certain award programs, which have contributed considerably to employee morale in the past. These programs would continue to be suspended in fiscal year 2004. We would also continue to severely limit funds allocated for variable expenses, such as overtime, travel, training, supplies and equipment. Further reductions would still be required in two areas directly affecting the public: agency staffing and information technology initiatives. Without additional funding, we will need to sharply reduce our staffing in fiscal year 2004. In addition, due to staffing reductions, the opportunities to achieve additional savings through automation will be diminished.

The Administration's proposed budget assumes that the RRB, as a trust fund agency, will continue to pay actual costs to the General Services Administration (GSA) for rental of space and services. The RRB has paid rent to GSA based on actual costs since fiscal year 1975. Consistent with this practice, the Administration's budget proposal for fiscal year 2004 includes funding based on actual costs. If GSA were to charge rent at the commercially equivalent rate in fiscal year 2004, the RRB's rental costs and total costs would increase by $3.7 million. We are currently negotiating with GSA officials on a long-term agreement that would continue the practice of paying actual costs for rental of space and services and provide for the possible payment of a fee to be applied against a given year's depreciation expense.

In addition to the requests for administrative expenses, the Administration's budget includes $119 million to fund the continuing phase-out of vested dual benefits, and $150,000 for interest related to uncashed railroad retirement checks.

REQUEST FOR ADDITIONAL FUNDING IN FISCAL YEAR 2004

We believe the President's proposed funding level is not sufficient to meet our statutory mission under the railroad retirement and railroad unemployment insurance programs. In order to maintain a minimum core of experienced staff and continue making information technology improvements, the RRB will need at least $102.5 million for agency administration in fiscal year 2004, excluding any costs for contracting with a non-governmental disbursement agent. In this regard, it appears unlikely that the transition to a non-governmental disbursement agent will occur during fiscal year 2004 due to complex issues which have surfaced during initial procurement actions concerning the costs and effectiveness of services available from non-governmental providers.

Accordingly, we request an appropriation of $102.5 million for agency administration in fiscal year 2004, which is $2.68 million above the Administration's proposed total funding level. This would effectively provide an additional $4.78 million for critical needs of this agency because our request does not include any funding for a non-governmental disbursement agent. We would use approximately $4.1 million of the increase for compensation and benefits, and the remaining amount for information technology investments. Even with these additional dollars, we would only be able to fund approximately 1,058 FTE's, which is 23 fewer than we expect to be able to fund in fiscal year 2003.

The efficient and timely administration of our Acts requires well-trained and experienced staff. Although the RRB has already suffered significant workforce reductions over the last few years, we have been able to maintain and even improve customer service. This has been accomplished using a core of experienced staff and productivity gains through technology. However, our staff has been seriously depleted due to the continued budget reductions and the aging of our workforce. We need additional funding in fiscal year 2004, to mitigate the expected loss of experienced staff by hiring and training new employees and to increase available resources for advances in information technology.

STRATEGIC MANAGEMENT OF INFORMATION TECHNOLOGY

Information technology initiatives in recent years have significantly improved operations and allowed the agency to reduce staffing in key areas. Ongoing and planned projects will further increase and enhance the efficiency and effectiveness of our systems for benefit payments and program administration. Key initiatives, which total $1,436,000 at the Administration's proposed budget level and $2,111,000

at the RRB's request level, can be grouped into two major categories, as described below.

Application design services.—Initiatives in this category focus on automation projects that are critical to our long-range strategy to promote better customer service through automation, while lowering the costs and increasing the efficiency of our operations. Specific investments planned for fiscal year 2004 include:

—*Information technology task orders ($250,000 at the President's proposed level, and an additional $150,000 at the agency request level)*.—This non-capital item represents funding to implement the President's goals for increasing private-sector competition in commercial-type activities. Contractor resources would be used on a task-order basis as an alternative to filling vacant positions.

—*Document imaging ($75,000)*.—This multi-year initiative is key to accomplishing our objective of paperless processing for claims operations. These funds will be used for licensing and performance-based contractual support.

—*System development tools ($25,000)*.—The RRB will require additional software development tools to remain current with the changing technologies in electronic commerce and to participate in interagency initiatives that seek to better coordinate data sharing among agencies.

—*E–Government initiatives (no funding provided at the President's proposed level, and $300,000 at the agency request level)*.—The RRB's Government Paperwork Elimination Act strategy continues to focus on providing electronic service options for the highest value and volume transactions. These transactions are core agency functions that support our primary mission of administering the benefit provisions of the Acts.

Technology infrastructure services.—These investments are required to establish a firm foundation for the planned technology advances and to maintain our operational readiness. The investments in this category for fiscal year 2004 include:

—*Standard workstation infrastructure ($300,000 at the President's proposed level, and an additional $25,000 at the agency request level)*.—Funding is required to continue the agency's policy of annually replacing and upgrading one-fourth of the agency's desktop computers, printers and related equipment and software needed to ensure an adequate work environment.

—*Network operations ($250,000)*.—This amount represents replacements and upgrades to network servers and related equipment needed to support a stable and efficient network throughout the agency.

—*Mainframe ($175,000 at the President's proposed level, and an additional $200,000 at the agency request level)*.—Funding is requested in fiscal year 2004 for a replacement mainframe processor or enterprise server that will be supported by the vendor for continued maintenance and updated software releases as needed. Funding at the President's proposed level would allow for payment for the first year of a multi-year lease of a replacement system. Funding at the agency request level would allow us to purchase, rather than lease, a system.

—*Enterprise storage lease payment ($161,000)*.—After a competitive selection process, an enterprise network storage system was installed to support the growing use of electronic services. This investment represents the second year of the capital lease for this equipment.

—*Information security ($150,000)*.—In order to support ongoing improvement of the overall security structure, we plan to implement intrusion detection systems and support services and to conduct a high-level vulnerability assessment using contractual assistance.

—*Enterprise architecture ($50,000)*.—Contractual assistance will be used to ensure the development of an efficient and effective implementation plan to close the gaps between the RRB's current and target enterprise architectures.

FINANCIAL STATUS OF THE TRUST FUNDS

Railroad Retirement Accounts.—As a result of transfers of $1.5 billion to the National Railroad Retirement Investment Trust, the net position of the railroad retirement accounts decreased by $1.1 billion in fiscal year 2002, to $18.7 billion. In fiscal year 2003, we have transferred an additional $17.75 billion to the Investment Trust.

In June 2002, we released the annual report on the railroad retirement system required by Section 22 of the Railroad Retirement Act of 1974 and Section 502 of the Railroad Retirement Solvency Act of 1983. The report, which reflects changes in benefit and financing provisions under the Railroad Retirement and Survivors' Improvement Act of 2001, addresses the 25-year period 2002–2026 and contains generally favorable information concerning railroad retirement financing. The report included projections of the status of the retirement trust funds under three employ-

ment assumptions. These indicated cash flow problems only under a pessimistic employment assumption, and then not until calendar year 2022.

Railroad Unemployment Insurance Accounts.—The equity balance of the railroad unemployment insurance accounts at the end of fiscal year 2002 was $15.8 million, a decrease of $24.3 million from the previous year. The RRB's latest annual report on the financial status of the railroad unemployment insurance system, issued in June 2002, was generally favorable. The report indicated that even as maximum daily benefit rates rise 50 percent (from $50 to $75) from 2001 to 2012, experience-based contribution rates are expected to keep the unemployment insurance system solvent, except for small, short-term cash flow problems in 2002 and 2003, requiring a loan from the Railroad Retirement Account. However, projections show a quick repayment of the loan even under the RRB's most pessimistic employment assumption. The average employer contribution rate remains well below the maximum throughout the projection period, but a 2.5 percent surcharge is now in effect and a 1.5 percent surcharge is expected for calendar year 2004. We did not recommend any financing changes based on this report.

In conclusion, we want to stress the RRB's continuing commitment to improving our operations and providing quality service to our beneficiaries. Thank you for your consideration of our administrative budget request for $102.5 million. We will be happy to provide further information in response to any questions you may have.

PREPARED STATEMENT OF THE RAILROAD RETIREMENT BOARD

Mr. Chairman and Members of the Subcommittee: My name is Martin J. Dickman, Inspector General of the Railroad Retirement Board (RRB). I would like to thank you, Mr. Chairman, and the members of the committee for your continued support for the Office of Inspector General. I wish to present our fiscal year 2004 appropriations request and to describe our planned activities.

The Office of Inspector General requests funding of $6,600,000 to ensure the continuation of its independent oversight of the RRB. The agency is responsible for managing benefit programs which paid $8.6 billion in retirement and survivor benefits to approximately 684,000 beneficiaries in fiscal year 2002 and an additional $99 million in railroad unemployment and sickness insurance benefits to 40,000 claimants. The RRB also administers Medicare Part B, the physician services aspect of the Medicare program, for qualified railroad retirement beneficiaries. Through this program, approximately $788 million in annual Medicare benefits are paid to approximately 571,000 beneficiaries.

In fiscal year 2004, the Office of Inspector General will continue to focus its resources on significant policy issues and operational areas. We will coordinate our efforts with agency management to identify and eliminate operational weaknesses. We will also continue our investigation of allegations of fraud, waste and abuse, and refer cases for prosecution and monetary recovery action.

We also request the removal of the prohibition on the use of funds for any audit, investigation or review of the Railroad Medicare program and the related reimbursement funds from the Centers for Medicare and Medicaid Services (CMS). The RRB is responsible for the administration of Medicare program activities including enrollment, premium collection, answering beneficiary inquiries and the monitoring of the contractor's performance in conjunction with CMS. The removal of the prohibition would allow us to carry out our statutory oversight responsibilities. The prohibition is contrary to the priorities set by the Administration and the Congress to reduce fraud in one of the largest Federal programs.

OFFICE OF AUDIT

Auditors will perform the audit of the RRB's 2003 financial statements and preliminary work for the 2004 financial statements to ensure the issuance of reliable financial information. The OIG will continue to recommend that management consider additional action to restructure the agency organization to address the overall control environment, a material weakness cited in the audits of the financial statements.

We will assign a high priority to the agency's monitoring of investment activities to ensure the statutory obligations of the Railroad Retirement Act and the Railroad Retirement and Survivors' Improvement Act are met. Because of our ongoing concerns on the investment of agency trust funds, we will seek legislative change to transfer the oversight and enforcement powers of investment activity from the agency to the OIG.

We will conduct the annual evaluation of the RRB's information systems security to meet the requirements of the Federal Information Security Management Act of

2002. We will also monitor the agency's information systems operations to determine if the agency is meeting the goals established in its Strategic Information Resources Management Plan and to ensure the agency is in compliance with the provisions of the Information Technology Management Reform Act.

We will ensure that network and system security safeguards are in place to protect the confidentiality of sensitive financial and personal information. We will continue our monitoring efforts of the RRB's document imaging activities and the expansion of paperless processing to ensure the integrity of records.

Auditors will review RRB benefit processes and procedures to identify ways to reduce administrative and adjudicative errors. They will offer recommendations to strengthen the agency's debt collection program to reduce the outstanding receivables that now total approximately $57.5 million.

OFFICE OF INVESTIGATIONS

The Office of Investigations (OI) identifies, investigates and presents cases for prosecution, throughout the United States, concerning fraud in RRB benefit programs. In fiscal year 2004, OI will continue to focus its resources on the investigation of cases with the highest fraud losses. OI currently has approximately 500 active investigations involving fraudulent benefit payments and fraudulent reporting with fraud losses of approximately $13 million. These cases involve all RRB programs that provide sickness and unemployment insurance benefits to injured or unemployed workers, retirement benefits, and disability benefits for workers who are disabled.

We will continue our efforts with program managers to address weaknesses in agency programs that allow fraudulent activity to occur, and will recommend changes to ensure program integrity.

We will concentrate our resources on cases with the highest fraud losses, those related to the RRB's retirement and disability programs as well as fraudulent reporting by railroad employers. We will continue our investigations of railroad employers and unions which submit fraudulent compensation and service reports to the RRB and do not submit the required contributions after they have been deemed to be covered employers under the Railroad Retirement Act and the Railroad Unemployment Insurance Act. These investigations typically have a significant impact on the RRB's trust funds.

In fiscal year 2004, we will continue to use the Department of Justice Affirmative Civil Enforcement (ACE) program for those cases which do not meet the criminal guidelines of U.S. Attorneys. Through this program, we are able to obtain civil judgements and recover trust fund monies for the RRB.

SUMMARY

In fiscal year 2004, the Office of Inspector General will continue its oversight of agency operations to improve the delivery of benefits to beneficiaries and their families. We will issue recommendations to improve the quality and integrity of benefit programs. We will also aggressively pursue individuals who engage in activities to fraudulently obtain RRB funds.

MISCELLANEOUS

PREPARED STATEMENT OF THE MOREHOUSE SCHOOL OF MEDICINE

Thank you for your leadership in securing $300,000 in the fiscal year 2003 Labor-HHS appropriations bill for the planning of a new Family Practice Center at the Morehouse School of Medicine.

As you begin to consider the Labor-HHS appropriations bill for fiscal year 2004, I request that the Committee provide $3,000,000 for this important project from the Health Resources and Services Administration's Health Care Facility Construction and Renovation Program.

Located in Atlanta, GA, Morehouse School of Medicine was founded in 1975 with the mission of recruiting, educating, and graduating students from socially and economically disadvantaged backgrounds for service as primary care physicians in medically underserved communities. Recent studies reflect the need for more primary care physicians, which places Morehouse School of Medicine on the cutting edge of needed change in health professions education. Nationally, MSM ranks among the top schools in the country in the percentage of graduates entering primary care. During the decade of the 1990's, MSM ranked first among all U.S. med-

ical schools, in three national surveys, in the percentage of graduates entering primary care in 1993, 1995, and 1999.

The medical school's Department of Family Medicine, which includes both academic and clinical functions, currently occupies approximately 10,000 gross square feet at Southwest Hospital Facility in Atlanta, Georgia. The existing facility of the department does not meet its current space needs. The expanded space that a new family practice facility will provide is necessary in order to maintain accreditation.

A new facility will enable our institution to further its commitment to the recruitment and training of students from disadvantaged communities. In addition, the new center will assist the medical school in addressing the longstanding health status disparities that exist among minority and medically underserved populations. Thank you very much for your consideration of this important request If you have any questions, please do not hesitate to contact me.

PREPARED STATEMENT OF THE UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY

Request summary.—The following is the testimony of the University of Medicine and Dentistry of New Jersey. We are seeking support for the following priority projects, which we believe, are consistent with the mission of this committee. The first is to expand the state-wide activities of the Institute for the Elimination of Health Disparities; the second is the continued development of the Child Health Institute of New Jersey in New Brunswick; and the third is to expand the New Brunswick based Dean and Betty Gallo Prostate Cancer Center outreach and cancer control programs to reach populations at risk in the Newark/northern New Jersey and Camden/southern New Jersey regions, and to strengthen the Center's clinical research programs. In addition, capital and program support is requested to create dedicated geriatric research space at our Center for Aging at the University's School of Osteopathic Medicine in Stratford. We also seek support for two initiatives to improve obstetrical and pre- and post-natal services in Newark and under served communities in southern New Jersey.

The University of Medicine and Dentistry of New Jersey (UMDNJ) is the largest freestanding public university of the health sciences in the nation. The University is located on five statewide campuses and contains three medical schools, and schools of dentistry, nursing, health related professions, public health and graduate biomedical sciences. UMDNJ comprises a University-owned acute care hospital, three core teaching hospitals, an integrated behavioral health care delivery system, a statewide system for managed care and affiliations with more than 200 health care and educational institutions statewide. No other institution in the nation possesses the resources that match our scope in higher education, research, health care delivery, and community service initiatives with federal, state and local entities.

We wish to express UMDNJ's appreciation to this committee for its support of the National Institutes of Health (NIH) and the important biomedical projects that are funded by the NIH, including those at UMDNJ. We appreciate this committee's strong support which is essential in maintaining the high standards of excellence in research and training sponsored by the NIH, and thank you for you actions in fiscal year 2003 which completed a doubling of NIH's budget over a five-year period. However any dramatic decline in the rate of growth for the NIH, as proposed by the Administration's fiscal year 2004 budget, threatens the momentum gained in medical research in recent years at a time when the nation continues to confront many health challenges. We urge the committee to maintain adequate funding levels for the NIH that will continue the progress of the last five years.

The University's priority projects are statewide in scope and include collaborations with our academic and health care partners. Our mission is focused on building "Centers of Excellence" that will expand our research, enhance our educational programs and provide access to quality health care services for all New Jerseyans. At the very foundation of this mission is our commitment to utilize the full strength of our research, educational and service programs in reducing and eliminating ethnic and health disparities. For that reason, UMDNJ's first priority again this year is the Institute for the Elimination of Health Disparities.

Despite the dramatic improvements in the health of the general population, the federal government has identified striking disparities in the overall health and life expectancy of racial and ethnic populations in the United States. Eliminating health disparities among different segments of the population is a primary goal of Healthy People 2010, the nation's public health agenda for this decade, as well as that of Healthy New Jersey 2010, the companion public health agenda for the state.

UMDNJ has long been recognized for its leadership in providing educational opportunities and health care services to under represented communities throughout our state. We are a leader in minority student and faculty recruitment and in the provision of services to underserved populations through our core and affiliated hospitals, clinics and community-based programs.

The University has focused its commitment to achieving better health for minority communities by creating the Institute for the Elimination of Health Disparities.

Congressional support for the Institute has resulted in $630,000 in directed appropriations over the last two years. With this support and matching funds provided by UMDNJ, the Institute is bringing together the nationally-recognized research, education and community outreach programs aimed at eliminating health disparities that are being conducted by UMDNJ's eight schools on five academic campuses.

The Institute is collaborating extensively with the Newark and Camden, NJ communities, cities with the greatest health disparity needs, to identify and implement strategies to improve community health. It also widely distributes information about health disparities to community law audiences, the research community, and healthcare providers across the state.

Continued support for the Institute is requested to broaden these initiatives and initiate new activities to address the existing gaps in health outcomes. Requested funding will expand the Institute's network of partnerships with grass-root organizations and agencies to provide academic-based leadership in developing health promotion and risk reduction strategies that respond to community needs and priorities. Support will also be utilized to provide start-up seed funding for faculty research projects that can be leveraged in seeking long-term program support. The Institute's research agenda seeks to better understand the socio-economic and medical causes for health disparities, and is directed toward federally identified priority areas, including infant mortality, cancer, cardiovascular disease, diabetes, HIV/AIDS and childhood immunizations. The Institute will continue its development of a statewide public information campaign about health disparities to better inform researchers, healthcare providers and the public about successful approaches to improve the health of minority and ethnic groups.

New Jersey, with a demographic profile and patterns of disparity that closely matches the nation's, can serve as an ideal site for federally sponsored research and education initiatives, with results applicable to the entire nation. UMDNJ is ideally positioned to lead New Jersey's efforts in eliminating racial and ethnic health disparities. We are respectfully seeking $4.5 million to continue the development of the Institute on behalf of the citizens of New Jersey and the nation.

Our second priority is the Child Health Institute of New Jersey.

The Child Health Institute of New Jersey (CHI), at UMDNJ-Robert Wood Johnson Medical School, is a comprehensive biomedical research center focused on the health and well being of children. Located on the New Brunswick campus of UMDNJ-Robert Wood Johnson Medical School, research conducted by the CHI will aid in the development of new treatments, therapies and cures for devastating and debilitating childhood disorders. Biomedical researchers will investigate the environmental, genetic and cellular causes of these diseases in infants and children through basic scientific studies. Some of the disorders that warrant immediate attention include asthma, muscular dystrophy, diabetes, birth defects and neurodevelopmental disorders including autism and spina bifida.

CHI has assembled more than $40 million in funding through a strong partnership among private, corporate and government entities. Support received for the construction of the Institute's 150,000 square foot building includes more than $6 million in general federal appropriations over the last four years, a $1.9 million grant from the National Center for Research Resources of the NIH in fiscal year 2000, and approximately $17 million from private foundations, corporations and individuals. The State of New Jersey has provided $3.7 million with a recurring annual appropriation of $1.7 million to support the debt service on the bonds sold to finance the remaining building costs. The CHI has raised an additional $15 million from corporations, foundations and individuals to support its scientific mission and goals. The CHI will increase the current research funding base of the UMDNJ-Robert Wood Johnson Medical School and strengthen research efforts with clinical departments at Robert Wood Johnson University Hospital (RWJUH), especially those involved with the new Bristol-Myers Squibb Children's Hospital at RWJUH.

The Child Health Institute has the expertise and the infrastructure in place to achieve major breakthroughs and discoveries that will lead to improvements and cures in childhood diseases. We are respectfully requesting $2 million for the purchase of analytical equipment, including laser scanning and photon microscopes, a mass spectrometer, and ventilated rack systems to further the development of the Child Health Institute of New Jersey facility.

As noted above, UMDNJ is committed to supporting activities that will help eliminate health disparities. This is why our next priority is the Dean and Betty Gallo Prostate Cancer Center.

The Cancer Institute of New Jersey (CINJ) was established in 1990 with a $10 million capital grant from the federal government. Over the past decade, CINJ has grown to become one of the nations most successful cancer institutes. As New Jersey's only NCI-Designated Comprehensive Cancer Center, CINJ joins an elite network of 41 cancer centers nationwide that are leaders in cancer treatment, research, and education.

One of CINJ's most significant accomplishments is the creation of the Dean and Betty Gallo Prostate Cancer Center, established with funding from the federal government. The Center honors the late Congressman Dean Gallo, who succumbed to prostate cancer in 1994. Located at the CINJ facility in New Brunswick, the Center has programs in public outreach, cancer control, prevention, basic and clinical research and treatment of prostate cancer. It is the only named center of its kind in the nation totally dedicated to the eradication of prostate cancer. The Center has secured more than $12 million in external public and private support in recent years.

Consistent with UMDNJ's priority goal of focusing on minority health issues, we are seeking support to expand the Gallo Center's public outreach and cancer control programs to regions where resources can be focused on critical minority and medically underserved communities who exhibit high incidence for prostate cancer.

The Gallo Center has already developed an extensive network of effective partnerships, working with groups such as the 100 Black Men of New Jersey, the Men's Health Network, and the Jewish Renaissance Foundation to offer prostate cancer education and screenings in minority communities. Additional resources are needed to expand the Gallo Center's education and prevention services to other regions of the state. Support will allow a major expansion of the Center's Public Outreach and Cancer Control initiatives to the Newark/northern New Jersey and Camden/southern New Jersey regions, and to targeted communities in Middlesex County to increase public awareness about early detection of prostate cancer, and to reduce its incidence among African-American, Latino, Asian-American and other undeserved populations most affected by this dreaded disease.

These outreach activities would also support research by CINJ investigators interested in improving outcomes by understanding how cultural issues affect cancer education, screening and treatment. Additional resources are needed to accelerate the Gallo Center's promising basic and clinical research programs that are investigating the molecular mechanisms involved in prostate cancer initiation and progression, and for translational studies to move laboratory discoveries into clinical practice. We respectfully request $3 million to expand the Gallo Center's Public Outreach and Cancer Control initiatives, and $3 million for the expansion of basic and clinical research programs.

Another priority initiative is the Geriatric Research Center.

The Center for Aging at the UMDNJ-School of Osteopathic Medicine (SOM) is an inter-disciplinary Center of Excellence in geriatric education, clinical care and research. The Center is nationally recognized as a leader in quality care for older individuals. Located within southern New Jersey, services are provided to the region's growing elderly population through the Center's network of ambulatory, acute care, long-term care and community-based programs. Attracting more researchers to the Center is critical to achieving national prominence as a Geriatric Research Center of Excellence.

The Center for Aging's complementary clinical service base provides opportunities for investigators to study the application of research findings among large cohorts of elderly individuals in varied settings over time. Based on an understanding of biology, behaviors, social and physical environments, policies and interventions can be developed which will enable our elderly population to live longer, more productive lives. The research programs of the Center will focus on cellular, biochemical and physiological aspects of aging. Research will be directed at the genetic determinants of both aging and diseases common in the elderly. The Geriatric Research Center will build on existing programs in nutrition, protein loss, injury, and Alzheimer's disease to expand basic science research programs in support of the established clinical and educational programs at the Center for Aging. A major obstacle is the critical lack of dedicated research space at the Center for Aging. We are therefore seeking $5 million in capital and program funds to support dedicated space and faculty for a Geriatric Research Center within the Center for Aging at the UMDNJ-School of Osteopathic Medicine.

To address other critical healthcare disparity needs, we are seeking support for two additional initiatives, both aimed at improving obstetrical and pre-and post-natal services in Newark and in southern New Jersey.

In Newark the infant mortality rate, and percentage of low-weight births, are both significantly higher than that of the state, and is particularly alarming among black infants. The University is seeking support for an initiative to partner with Newark community health centers to target women at greatest risk for poor pregnancy outcomes for early enrollment into prenatal care. Early enrollment into prenatal care provides the best opportunity to identify and address behavioral practices and other maternal factors that adversely affect pregnancy outcomes. Collaborating on this initiative will be the UMDNJ Institute for the Elimination of Health Disparities, UMDNJ-University Hospital, and UMDNJ-New Jersey Medical School.

Requested funding will also support renovations at UMDNJ-University Hospital in Newark to upgrade outdated labor and delivery facilities. Proposed renovations will improve patient flow and replace the current multi-transfer system between the triage, labor, delivery and recovery areas into a combined labor/delivery/recovery suite. Increased space allocations for labor and delivery rooms, and centralized nursing stations are incorported into the design to enhance patient comfort and increase service efficiency. We respectfully seek support of $8.15 millon in capital and program funds for this initiative.

In southern New Jersey, a rising birthrate is creating greater demand for expanded delivery and pre- and post-natal services at a time when gaps in such services are growing. The UMDNJ-School of Osteopathic Medicine is seeking support to address immediate and long-range needs for improving access to maternity care, as well as pre- and post-natal care and education in the region's underserved communities. University supported medical liability insurance will be leveraged to "seed" underserved areas with new OB/GYN providers, and help ensure that all hospitals in the region can provide 24/7 coverage for delivery services. Pre- and post-natal education and awareness programs will be conducted collaboratively with the Institute for the Elimination of Health Disparities. Support of $2.5 million is respectfully requested for this initiative.

Again, we thank you for this opportunity to submit testimony on behalf of UMDNJ's priority initiatives that will advance research, education and treatment of diseases and disabilities that most seriously affect children, the elderly and minority populations, and will go a long way toward eliminating health disparities in the areas of cancer, obstetrical and pre- and post-natal care. We also thank this committee for its leadership and its continued support for our programs.

PREPARED STATEMENT OF THE AMERICAN MUSEUM OF NATURAL HISTORY

ABOUT THE AMERICAN MUSEUM OF NATURAL HISTORY

The American Museum of Natural History [AMNH] is one of the nation's preeminent institutions for scientific research and public education. Since its founding in 1869, the Museum has pursued its mission to "discover, interpret, and disseminate—through scientific research and education—knowledge about human cultures, the natural world, and the universe." It is renowned for its exhibitions and collections, and with nearly four million annual visitors—approximately half of them children—its audience is one of the largest, fastest growing, and most diverse of any museum in the country. Museum scientists conduct ground breaking research in fields ranging from all branches of zoology, comparative genomics, and informatics to earth, space, and environmental sciences and biodiversity conservation.

Today more than 200 Museum scientists with internationally recognized expertise, led by 46 curators, conduct laboratory and collections-based research programs as well as fieldwork and training. Scientists in five divisions (Anthropology; Earth, Planetary, and Space Sciences; Invertebrate Zoology; Paleontology; and Vertebrate Zoology) are documenting changes in the environment, making new discoveries in the fossil record, and describing human culture in all its variety. In the Museum's Institute for Comparative Genomics, established in 2001, researchers are mapping the genomes of non-human organisms as well as creating new computational tools to retrace the evolutionary tree. The Museum also conducts graduate training programs in conjunction with a host of distinguished universities, supports doctoral and postdoctoral scientists with highly competitive research fellowships, and offers talented undergraduates an opportunity to work with Museum scientists.

The AMNH collections of some 32 million natural specimens and cultural artifacts are a major scientific resource, providing the foundation for the Museum's interrelated research, education, and exhibition missions. They often include endangered

and extinct species as well as many of the only known "type specimens," or examples of species by which all other finds are compared. Within the collections are many spectacular individual collections, including the world's most comprehensive collections of dinosaurs, fossil mammals, Northwest Coast and Siberian cultural artifacts, North American butterflies, spiders, Australian and Chinese amphibians, reptiles, fishes, and one of the world's most important bird collections. Collections such as these provide vital data for Museum scientists as well as for more than 250 national and international visiting scientists each year.

Permanent and temporary exhibits—from the Rose Center for Earth and Space to *The Genomic Revolution* (see below)—are among the Museum's most potent educational tools for promoting public education, science literacy, and lifelong learning. *Science Bulletins*—high definition video wall displays—present breaking science news, images, and data in the Museum's new Halls of Biodiversity, Planet Earth, and the Universe. The Education Department builds on these exhibition and science resources to offer rich programming dedicated to increasing scientific literacy, encouraging students to pursue science and museum careers, and to providing a forum for exploring the world's cultures. The Museum is also reaching beyond its walls: through its National Center for Science Literacy, Education, and Technology, launched in 1997 in partnership with NASA, it is exploiting new technologies to bring materials and programs into homes, schools, museums, and community organizations around the nation.

COMPARATIVE GENOMICS INITIATIVE: RESEARCH, TRAINING, EDUCATION AND OUTREACH RESOURCES

The American Museum shares with DHHS and the Department of Education a fundamental commitment to improving the nation's health and education and advancing the research, training, facilities, and technology that support them. The Museum is deeply engaged in the area of comparative genomics, and it is in this vital area that the Museum seeks to partner with the DHHS/HRSA and the Department of Education.

Genomic Science and Training Resources

DHHS leads the nation's health-related research and genome science, advanced sequencing technologies, instrumentation, and facilities. The American Museum, in turn, is home to a preeminent molecular research and training program and leading science education and outreach efforts. In the era of genomics, museum collections have become critical baseline resources for the assessment of genetic diversity of natural populations; studying genomic data in a natural history context makes it possible to more fully understand the impacts of new discoveries in genomics and molecular biology. Genomes of the simplest organisms provide a window into the fundamental mechanics of life, and understanding their natural capabilities can help solve challenges in biodefense, medicine, and health care. In the Museum's molecular laboratories, in operation now for eleven years, more than 40 researchers in molecular systematics, conservation genetics, and developmental biology conduct genetic research on a variety of study organisms. The labs also nourish the Museum's distinguished training programs that serve up to 80 undergraduates, doctoral, and postdoctoral trainees annually.

Frozen Tissue Collection

In support of its molecular program, the Museum has launched an expansion of its collections to include biological tissues and isolated DNA preserved in a super-cold storage facility. Because this collection preserves genetic material and gene products from rare and endangered organisms that may become extinct before science fully exploits their potential, it is an invaluable resource for research in many fields including genetics, comparative genomics, and biodefense. Capable of housing one million specimens, it will be the largest super-cold tissue collection of its kind. In the past two years, 15,000 specimens not available at any other institute or facility have already accessioned. At the same time, the Museum is pioneering the development of collection and storage protocols for such collections. To maximize use and utility of the facility for researchers worldwide, the Museum is also developing a sophisticated website and online database that includes collection information and digitized images.

Cluster Computing

The Museum also has exceptional capacity in parallel computing, an essential enabling technology for phylogenetic (evolutionary) analysis and intensive, efficient sampling of a wide array of study organisms. Museum scientists have constructed an in-house 560-processor computing cluster, and are in the process of upgrading

it to 128 dual CPU nodes with 2 Gb/sec Myrinet interconnections. It is the fastest parallel computing cluster in an evolutionary biology laboratory and one of the fastest installed in a non-defense environment.

Museum investigators have taken a leadership role in developing and applying new computational approaches to deciphering evolutionary relationships through time and across species; their pioneering efforts in cluster computing, algorithm development, and evolutionary theory have been widely recognized and commended for their broad applicability for biology as a whole. The bioinformatics tools Museum scientists are creating will not only help to generate evolutionary scenarios, but will also inform and make more efficient large genome sequencing efforts. Many of the parallel algorithms and implementations (especially cluster-based) will be applicable in other informatics contexts such as annotation and assembly, breakpoint analysis, and non-genomic areas of evolutionary biology as well as in other disciplines.

Education and Outreach

The Museum matches these outstanding science resources with an ambitious genomics education and outreach capacity. The Education Department provides standards-based curricular materials and on-site programs for school and camp groups from throughout the region, Moveable Museums that travel to schools and community sites, a model after-school program, award-winning online educational resources, and lectures, workshops, and field excursions for adult learners. Its award-winning online professional development program for science teachers—Seminars on Science—includes subjects in genetics, genomics, and genethics. These and other programs attract more than 500,000 students and teachers on school visits and nearly 5,000 teachers for special professional development opportunities. The Museum's website (www.amnh.org) also serves to reach online audiences nationally, offering in-depth virtual "tours" of exhibitions; features on curators, expeditions, and current research; access to collections; and links to the AMNH digital library.

COMPARATIVE GENOMICS INITIATIVE

Building on these unique strengths in genomics science, training, and education, and in concert with the health, education, and training goals of DHHS and the Department of Education, in 2001 the Museum launched an ambitious initiative—The Institute of Comparative Genomics. Equipped with the parallel computing facility, molecular labs with DNA sequencers, ultra-cold storage units, vast biological collections, and researchers with expertise in the methods of comparative biology, as described above, the Institute is positioned to be one of the world's premier facilities for mapping the genome across a comprehensive spectrum of life forms. Working collaboratively with New York's outstanding biomedical and educational institutions, it is conducting research and training in such critical areas as microbial genomics and biocomputation. Complemented by the Museum's planned education and outreach utilizing innovative educational technologies, the Institute will constitute a national resource of unique scope and range.

The Institute is establishing a distinguished research and training record. Museum scientists have pioneered theoretical and analytical approaches and are leading major new international research projects in assembling the "tree of life." They have developed efficient software for the interpretation of microarray data, which can be used to support more accurate diagnosis of pathogens, and novel methodologies and algorithms for analyzing genomic, chromosomal, and other data to discern evolutionary relationships among organisms. Current projects include sequencing pathogens and, with NIH and DOE support, tracing the evolution of pathogenicity and transfer of disease-causing genes over time and between species.

In developing the Institute, the Museum plans to expand its curatorial range in microbial systematics and the program that now trains dozens of graduate students every year; utilize the latest sequencing technologies; employ parallel computing applications to solve combinatorily complex problems involving large real work datasets; and grow the super-cold tissue collection. It plans to expand and renovate lab space and facilities into a state-of-the-art training and research laboratory to accommodate additional students and researchers.

Along with the research and training components of the genomics initiative, the Museum is using education technologies to promote understanding of genomics. The Museum shares the Department of Education's commitment to improving the nation's education through teacher quality, providing additional educational opportunities outside of the classroom, and harnessing new technologies to enhance instruction, and its education and outreach plans for the Institute of Comparative Genomics will help to advance these shared goals.

Its public education accomplishments to date include the landmark exhibition, *The Genomic Revolution*, open from June through December 2001. The exhibition,

attended by approximately 500,000 visitors and now touring nationally, examined the revolution taking place in molecular biology and its impact on modern science and technology, natural history, biodiversity, and our everyday lives. The Museum has also hosted several conferences on important topics related to genomics: *Sequencing the Human Genome: New Frontiers in Science and Technology*, an international conference featuring leading scientists and policymakers in Fall 2000; *Conservation Genetics in the Age of Genomics in Spring 2001*; and *New Directions in Cluster Computing* in June 2001, which explored how parallel computing enables genomic science and other fields. June 2002, we hosted an international conference examining current knowledge of life's history, *Assembling the Tree of Life: Science, Relevance, and Challenges.*

Using cutting-edge education and exhibition technologies and distance learning applications, the Museum plans to expand and diversify the reach of our genomics related professional development, educational materials, and exhibition-related programming. Specifically, the Museum's plan to develop a suite of standards-based curricular materials and programs related to genome science for online distribution to educators nationwide; to adapt and extend our successful Seminars on Science model of online professional development courses for K–12 teachers nationwide in subjects related to genomics; to enhance exhibition technologies and include a focus on genomics in our *Science Bulletins*; and to pilot a distance education initiative live from the Museum's halls and classrooms that will include a selection of regular interactive classes, professional development mini-series, and special live events, all designed to promote genomics teaching and learning in New York City, the region, and the country.

GENOMICS INITIATIVE PARTNERSHIP

The Museum seeks $7 million in fiscal year 2004 to partner with DHHS/HRSA and the Department of Education in furthering its genomics research, training, and education initiative.—In so doing, the Museum will contribute its participatory share with funds from nonfederal as well as federal sources, including funds raised through the Museum's own efforts from the City and State of New York as well as private contributions and foundations. In partnership with these agencies, the Museum will be poised to contribute its unique resources to the nation's health research and education missions: to advancing basic research and training in genomics, which has its potential applications in medicine, biomedical research, and clinical treatment; and to promoting science education and science literacy in the era of genomics. As a federal partnership, the Museum proposes two interrelated approaches:

—$5 million as a facilities/instrumentation initiative, building on our already extensive investments, to construct a NATIONAL RESEARCH AND TRAINING LABORATORY FOR COMPARATIVE AND MICROBIAL GENOMICS. In partnership with DHHS/HRSA, the Museum plans to expand its existing Molecular Program facilities into a state-of-the-art molecular laboratory for research and training activities. The requested support will be used towards constructing a cutting-edge laboratory and upgrading HVAC and plumbing in 6,000 sq. feet of existing lab, office, and storage space. The expanded facility will provide up-to-date work space and instrumentation for graduate and postdoctoral trainees as well as senior scientists.

—$2 million as an education technology initiative. In partnership with the Department of Education, the Museum will expand professional development, create K–12 curriculum materials, enhance exhibition technologies, incorporate a focus on genomics in the Museum's Science Bulletins, develop a distance education initiative, and launch online learning resources to promote teaching and learning nationwide about genomic science.

In partnership, the American Museum of Natural History and the Departments of Health and Human Services and Education will be positioned to leverage their unparalleled resources to advance shared goals for improving the nation's health and welfare and promoting its research and education in the genomics era.

LIST OF WITNESSES, COMMUNICATIONS, AND PREPARED STATEMENTS

SUBJECT INDEX

DEPARTMENT OF EDUCATION

OFFICE OF THE SECRETARY

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